

**Dossier and Robust Summaries for
Benzene, 1,1'-[1,2-
ethanediylbis(oxy)]bis[2,4,6-tribromo-
CAS No. 37853-59-1**

December 11, 2002

Dossier and Robust Summaries for Benzene, 1,1'-[1,2-ethanediylbis(oxy)]bis[2,4,6-tribromo-

Existing Chemical : ID: 37853-59-1
CAS No. : 37853-59-1
TSCA Name : Benzene, 1,1'-[1,2-ethanediylbis(oxy)]bis[2,4,6-tribromo-
Product name : FF-680

Producer Related Part

Company : Great Lakes Chemical Corporation
Creation date : 20.08.2002

Substance Related Part

Company : Great Lakes Chemical Corporation
Creation date : 20.08.2002

Memo :

Printing date : 18.09.2002
Revision date : 11.12.2002
Date of last Update : 11.12.2002

Number of Pages : 51

Chapter (profile) : Chapter: 1, 2, 3, 4, 5, 7
Reliability (profile) : Reliability: without reliability, 1, 2, 3, 4
Flags (profile) :

1. General Information

Id 37853-59-1
Date 18.09.2002

1.0.1 OECD AND COMPANY INFORMATION

Great Lakes Chemical Corporation
West Lafayette, IN 47906

1.0.2 LOCATION OF PRODUCTION SITE

Great Lakes Chemical Corporation
West Lafayette, IN 47906

1.0.3 IDENTITY OF RECIPIENTS

1.1 GENERAL SUBSTANCE INFORMATION

Substance type	: organic
Physical status	: solid
Purity	: ca. 100 % w/w
Remark	: A purity of 100% was given in the Great Lakes Chemical Corp. MSDS.
Reliability	: (1) valid without restriction

05.09.2002

1.1.0 DETAILS ON TEMPLATE

1.1.1 SPECTRA

1.2 SYNONYMS

1,2- Bis(tribromophenoxy) ethane
22.08.2002

1,2-Bis(2,4,6-tribromophenoxy)ethane
22.08.2002

benzene, (1,1'-[1,2-ethanediylbis(oxy)]bis[2,4,6-tribromo-])
22.08.2002

1.3 IMPURITIES

1.4 ADDITIVES

1.5 QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.7 USE PATTERN

Use : Flame retardant for thermoplastics and thermoset resin systems
Type : industrial
Category : Textile processing industry
Reliability : (1) valid without restriction
05.09.2002

1.7.1 TECHNOLOGY PRODUCTION/USE

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.9 SOURCE OF EXPOSURE

1.10.1 RECOMMENDATIONS/PRECAUTIONARY MEASURES

1.10.2 EMERGENCY MEASURES

1.11 PACKAGING

1.12 POSSIB. OF RENDERING SUBST. HARMLESS

1.13 STATEMENTS CONCERNING WASTE

1.14.1 WATER POLLUTION

1.14.2 MAJOR ACCIDENT HAZARDS

1.14.3 AIR POLLUTION

1.15 ADDITIONAL REMARKS

1.16 LAST LITERATURE SEARCH

1.17 REVIEWS

1.18 LISTINGS E.G. CHEMICAL INVENTORIES

2.1 MELTING POINT

Value : ca. 224 °C
Sublimation :
Method : Directive 84/449/EEC, A.1 "Melting point/melting range"
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Reliability : (2) valid with restrictions. Purity of the test material is not known.
18.09.2002 (22)

Value : ca. 213.6 °C
Sublimation :
Method : other
Year : 2002
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : EPIWIN MPBPWIN estimates melting point by several methods (adapted Joback, Gold and Ogle). The melting point selected is the weighted value of these methods.
Source : EPIWIN MPBPWIN (v1.40).
Reliability : (2) valid with restrictions. Data were obtained by modeling.
29.08.2002

2.2 BOILING POINT

Value : ca. 502 °C at 1016 hPa
Decomposition :
Method : other
Year : 2002
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : EPIWIN MPBPWIN uses the adapted Stein and Brown method to estimate boiling point.
Source : EPIWIN MPBPWIN (v1.40).
Reliability : (2) valid with restrictions. Data were obtained by modeling.
09.09.2002

2.3 DENSITY

Type : relative density
Value : = 2.6 at °C
Method : other
Year : 2001
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : The test material was a commercial product that contained 100% CAS No. 37853-59-1 according to the MSDS.
Reliability : (2) valid with restrictions. Methodological details were not provided.
16.09.2002 (19)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value	: < .000001 hPa at 25° C
Decomposition	:
Method	: other (calculated)
Year	: 2002
GLP	: no
Test substance	: as prescribed by 1.1 - 1.4
Remark	: EPIWIN MPBPWIN estimates vapor pressure using melting point or boiling point. The boiling point was estimated based on molecular structure. The melting point was obtained from Kirk Othmer Encyclopedia of Chemical Technology 4th ed.
	The vapor pressure selected by the estimation program was 1.79E -10 mm Hg (Modified Grain Method).
Reliability	: (2) valid with restrictions. Data were obtained by modeling.
09.09.2002	(15)

2.5 PARTITION COEFFICIENT

Log pow	: = 3.137 at ° C
Method	: other (measured)
Year	: 1977
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Method	: The method described by Leo, Hansch and Elkins (Leo, A, Hansch C, and Elkins D. 1971. Partition coefficients and their uses. Chem. Rev., 71: 537-8) was followed.
Remark	: It is assumed that the test was performed at room temperature.
Result	: The partition coefficient of MC -680 in n-octanol/water was determined to be 1373 (the average of two values in the first sampling and two values in the second sampling for two different concentrations). The log Pow is therefore 3.137.
Test condition	: C14 labeled MC-680 [1,2-bis(2,4,6-tribromophenoxy)ethane] (CAS No. 37853-59-1), with a specific radioactivity of 23 mCi/mM was prepared by Pathfinder Laboratories, Inc., St. Louis, Mo. Radiochemical purity was greater than 98%. The method of Leo, Hansch, and Elkins was followed. Each chemical was studied at 2 concentrations. A suitable amount of the C14 labeled chemical was delivered to a 15 ml centrifuge tube, the solvent was evaporated under nitrogen, and then 2 ml of n -octanol was added to dissolve the chemical. Five ml of water was added to the tube and the tube was then covered with a parafilm. The tube was inverted 200 times in about 5 minutes and was then centrifuged at 3,000 revolutions per minute for 15 minutes. After centrifugation, 0.1 ml of the organic phase and 1 ml of the water phase was counted in Aquasol. The tube inversion and sample taking was repeated once. Duplicate samples were counted using Searle Mark III Liquid Scintillation System Model 6880. An external standard pulse method was used to determine sample quenching. Counting efficiency, usually between 85-88%, was determined by an on-line computation program.
	Concentrations of MC-680 in the n -octanol and water phases were determined and the partition coefficients were calculated.
Reliability	: (2) valid with restrictions. The test temperature and the analytical purity of MC-680 were not specified.
16.09.2002	(23) (29)
Log pow	: ca. 9.14 at ° C
Method	: other (calculated)

2. Physico-Chemical Data

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Date 18.09.2002

Year : 2002
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : EPIWIN KOWWIN estimates Log Kow by identifying Log Kow fragments in the molecular structure. Numerical contributions from each fragment are summed up to obtain a total numerical value, as modified by a program equation constant.
Reliability : (2) valid with restrictions. Data were obtained by modeling.
29.08.2002 (14)

2.6.1 WATER SOLUBILITY

Value : = .2 mg/l at 25 ° C
Qualitative :
Pka : at 25 ° C
PH : at and ° C
Method : other
Year : 1978
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Result : The water solubility at 15 degrees was 0.26 and 0.06 for individual runs, with a mean value of 0.16 mg/l. At 25 degrees C the values were 0.19 and 0.21 mg/l (mean value 0.2 mg/l). At 35 degrees C the values were 0.09 and 0.06 mg/l (mean value 0.08 mg/l).
Test condition : C14 radiolabeled test substance was diluted with toluene solvent to achieve the appropriate specific radioactivity (5119 dpm/microgram). An appropriate amount of the solution containing 107 microgram of test substance was placed in a polyallomer centrifuge tube. Six tubes were prepared for the study. A gentle stream of nitrogen was used to remove the solvent from the tubes. Twenty ml of distilled water was added to each tube, and then caps were placed over each tube and tightened. The tubes were placed in a water bath and shaken overnight at 35 deg C. The six tubes were then centrifuged at 12,000 x G for 1 hour: 2 tubes at 15 deg C, 2 tubes at 25 deg C, and 2 tubes at 35 deg C. After centrifugation, duplicate 2 ml of the solution were taken for radioassay. All liquid samples were counted in Han difluor scintillation solution. A Mark III liquid Scintillation System Model 6880 was used for radiocarbon counting. Sample quenching was determined by an external standard pulse method. Counting efficiency, usually between 70 -85%, was determined by an on-line computation program. The water solubility was checked both 1 and 2 hours after centrifugation, with no difference observed.
Test substance : C14 radiolabeled 1,2-bis(2,4,6-tribromophenoxy)ethane (CAS No. 37853-59-1). Radiochemical purity >98%.
Reliability : (2) valid with restrictions. Purity of the test substance was not noted.
16.09.2002 (43)

Value : ca. .338 mg/l at 25 ° C
Qualitative :
Pka : at 25 ° C
PH : at and ° C
Method : other
Year : 2002
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : EPIWIN WSKOW calculates water solubility using a regression equation and based on the Log Kow. The value used for the log Kow (3.317) is an actual, measured value obtained by Leo et al., Chem Rev, 71: 537-8, 1971 (rather than estimated by EPIWIN).
Reliability : (2) valid with restrictions. Data were obtained by modeling.
16.09.2002 (16)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

Result	: other: minimum ignition energy of powder >10J
Method	: other: Vertical Tube Apparatus - BS5958: Part 1: 1991 Control of Undesirable Static Electricity.
Year	: 1991
GLP	: no
Test substance	: as prescribed by 1.1 - 1.4
Remark	: Summary: FF-680 was tested for minimum ignition energy in a vertical tube apparatus. The sample had a particle size <75 um as determined by a Gilson sieve shaker. The minimum ignition energy was >10J indicating low sensitivity to ignition.
Source	: Great Lakes Chemical Corporation, West Lafayette, Indiana
16.09.2002	(7)

2.11 OXIDIZING PROPERTIES

2.12 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

Type	: other: Applied to a silica gel surface
Light source	: other: UV light in a Chromato -Vue TLC Viewing Box
Light spect.	: nm
Rel. intensity	: based on Intensity of Sunlight
Conc. of subst.	: .74 g/l at degree C
Direct photolysis	
Half-life t _{1/2}	: .4 day
Degradation	: % after
Quantum yield	:
Deg. Product	:
Method	: other (measured)
Year	: 1979
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Result	: On a silica gel surface, FM-680 [1,2-bis(2,4,6-tribromophenoxy)ethane] (CAS No. 37853-59-1) was degraded rapidly when irradiated with uv light. The disappearance of FM-680 from the silica gel surface followed a biphasic curve. Initially the substance decreased rapidly with a half-life of about 0.4 day. After 1 day of uv exposure, however, the degradation rate decreased. The half-life of the second phase was determined to be 1.7 days. After 10 days of exposure, 37% of the C14 was recovered. According to the study report author, some of the test substance and degradation products probably volatilized from the plate surface. At least 4 degradation products were detected by TLC analysis. Three were not identified. One of these reached a maximum concentration after one day of 48% of applied C14. This unknown was assumed to be polymerized product. A fourth degradation product was positively identified by mass spectra to be 2-(2',4',6'-tribromophenoxy)ethanol, which comprised 0.5 to 6% of the applied radiocarbon. This and other degradation products appeared to be transitory, increasing in concentration initially, then gradually disappearing.
Test condition	: C14 radiolabeled 1,2-bis(2,4,6-tribromophenoxy)ethane-phenyl UL-C14, with a specific activity of 23 mCi/mmol and a radiochemical purity greater than 98%, was prepared by Pathfinder Labs, Inc., St. Louis, Missouri.

A silica gel G plate without fluorescence indicator (20 x20 cm, 0.25mm thickness) was evenly marked with 9 pencil marks on one side of the plate. Five microliters of the radiolabeled test substance in toluene solution (0.74 micrograms/microliter) was applied to each mark. The plate was then exposed to uv light in a Chromato-Vue TLC Viewing Box. Each spot was exposed for a predetermined length of time, and then each was covered with aluminum foil.

After all of the spots had been exposed, the plate was developed in a solvent which consisted of methylene chloride/n-propyl alcohol (95:5) and then subjected to radioautography. The resolved radioactive spots were scraped from the plate and placed in scintillation vials. Two ml of methanol were added to each vial, shaken for 1 hour, and then 10 ml of Handifluor counting solution were added for radioassay.

A Mark III Liquid Scintillation system, Model 6880, was used for radiocarbon counting. Sample quenching was determined by the external standard pulse method. Counting efficiency, usually between 70 -85%, was determined by an on-line computation program. Mass spectra were obtained by direct inlet probe in either the electronic impact (EI, 70 eV) or chemical ionization (CI, methane) mode (Hewlett Packard Model 5982A Quadrupole MS). Data output from the MS was monitored with a Hewlett Packard Model 5934A Dual Disc Data System.

3. Environmental Fate and Pathways

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Reliability 16.09.2002	: Packard Model 5934A Dual Disc Data System. (2) valid with restrictions. Purity of the test substance was not given.	(44)
Type	: air	
Light source	: Sun light	
Light spect.	: nm	
Rel. intensity	: based on Intensity of Sunlight	
Indirect photolysis		
Sensitizer	: OH	
Conc. of sens.	:	
Rate constant	: ca. .000000000014857 cm ³ /((molecule*sec)	
Degradation	: ca. 50 % after 8.6 hour(s)	
Deg. Product	:	
Method	: other (calculated)	
Year	: 2002	
GLP	: no	
Test substance	: as prescribed by 1.1 - 1.4	
Remark	: EPIWIN AOP determines individual rate constants for hydroxyl radical reaction with each molecular fragment, and then sums these contributions to obtain an overall rate constant. The half-life is calculated from the rate constant assuming pseudo first order kinetics and a constant concentration of OH radical.	
Reliability 29.08.2002	: (2) valid with restrictions. Data were obtained by modeling.	(10)

3.1.2 STABILITY IN WATER

Type	:	abiotic																								
t1/2 pH4	:	at degree C																								
t1/2 pH7	:	at degree C																								
t1/2 pH9	:	at degree C																								
Deg. Product	:																									
Method	:																									
Year	:																									
GLP	:	no data																								
Test substance	:	other TS: VC 680.																								
Remark	:	The robust summary preparer interprets the resulting data to indicate that hydrolysis occurred primarily within the first 6 hours of reflux, the time interval at which the pH changed rapidly from 7.6 to 8.9 units.																								
		Hydrolysis is not expected to occur at a significant rate in neutral water at ambient temperatures, because the test substance has very low solubility in water, and because the test substance does not possess functional groups readily subject to hydrolysis. Neither aromatic bromo groups nor ether linkages are readily subjectable to hydrolysis under these conditions.																								
Result	:	The pH values at representative times were:																								
		<table><tr><td>Time</td><td>pH</td><td>Time</td><td>pH</td></tr><tr><td>0.0</td><td>7.6</td><td>30.0</td><td>8.4</td></tr><tr><td>1.7</td><td>8.8</td><td>118.0</td><td>8.4</td></tr><tr><td>6.0</td><td>8.9</td><td>142.0</td><td>8.5</td></tr><tr><td>22.0</td><td>8.4</td><td>166.0</td><td>8.4</td></tr><tr><td>25.0</td><td>8.7</td><td>190.0</td><td>8.4</td></tr></table>	Time	pH	Time	pH	0.0	7.6	30.0	8.4	1.7	8.8	118.0	8.4	6.0	8.9	142.0	8.5	22.0	8.4	166.0	8.4	25.0	8.7	190.0	8.4
Time	pH	Time	pH																							
0.0	7.6	30.0	8.4																							
1.7	8.8	118.0	8.4																							
6.0	8.9	142.0	8.5																							
22.0	8.4	166.0	8.4																							
25.0	8.7	190.0	8.4																							
		Net change 1.3																								
Test condition	:	The rate of hydrolysis for VC 680 in water at 100 degrees C was determined . The test was conducted using 25 parts of sample and 75 parts of water heated at reflux temperature of approximately 100 degrees C. Periodically the pH of the mixture was measured using a pH meter.																								

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The tests were terminated after 7 days or when the pH of the reaction mixture reached the value of 1.0 units.

The pH of the water used initially measured 6.3 units. The pH value listed at 0.0 hours was measured after the reaction mixture had stirred for 0.5 hrs at ambient temperature.

Reliability	:	(3) invalid	
	:	A reliability rating of 3 is assigned because the purity of the test substance was not noted, the chemical identity was not provided, no quality assurance was noted in the study, and the method used to determine hydrolysis rate was imprecise.	
16.09.2002			(28)
Type	:	abiotic	
t1/2 pH4	:	at degree C	
t1/2 pH7	:	at degree C	
t1/2 pH9	:	at degree C	
Deg. Product	:		
Method	:	other (calculated)	
Year	:	2002	
GLP	:	no	
Test substance	:	as prescribed by 1.1 - 1.4	
Remark	:	EPIWIN H YDROWIN cannot estimate a hydrolysis rate constant for this molecule. This substance does not contain functional groups known to be easily hydrolyzed.	
Result	:	no data	
Reliability	:	(3) invalid	
03.09.2002			(13)

3.1.3 STABILITY IN SOIL

3.2 MONITORING DATA

Remark	:	Soil samples collected at an industrial site (Velsicol, El Dorado, AK) in April 1977 contained 1,2-bis(2,4,6 -tribromophenoxy)ethane at a maximum concentration of 253 micrograms/kg.	
16.09.2002			(27)
Remark	:	Sediment samples collected at an industrial site (Velsicol, El Dorado, AK) in April 1977, contained 1,2-bis(2,4,6 -tribromophenoxy)ethane at a maximum concentration of 466 micrograms/kg.	
16.09.2002			(27)
Remark	:	Air particulate samples collected at an industrial site (Velsicol, El Dorado, AK) in April 1977, contained 1,2-bis(2,4,6 -tribromophenoxy)ethane at concentrations from 39 to 183 ng/cubic meter.	
16.09.2002			(27)

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type	:	fugacity model level III
Media	:	water - air
Air (level I)	:	.0765
Water (level I)	:	1.17
Soil (level I)	:	
Biota (level II / III)	:	61.5
Soil (level II / III)	:	37.3

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Method	: other
Year	: 2002
Method	: Inputs to model were molecular weight of 687.64, Henry's Law Constant of 4.25 E-007 atm · m ³ /mol from HENRYWIN program, vapor pressure of 1.79 E-10 mm Hg from MPBPWIN program, melting point of 224 deg C inputted from Kirk Othmer Encyclopedia of Chemical Technology, log Kow of 9.15 from EPIWIN KOWWIN program, and a soil Koc of 5.79E+008 from PKOC program.
Remark	: The model predicts that based on very low water solubility and very low vapor pressure, minimal amounts of the test substance will enter or remain in the atmosphere or hydrosphere. Most of the test substance will partition preferentially to soil or biota.
Reliability 09.09.2002	: (2) valid with restrictions. Data were obtained by modeling.

(12)

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	: aerobic
Inoculum	: other bacteria: microorganisms from fresh settled sewage and garden soil acclimated for 18 days to MC -680 in medium.
Contact time	: 183 day
Degradation	: <= 1.41 % after 211 day
Result	: other: not readily biodegradable
Control substance	: other: 14-C-glucose
Kinetic	: % %
Deg. Product	:
Method	: other
Year	: 1976
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Result	: Total 14C-activity, liberated as 14CO ₂ , was 2.67 x 10E6 dpm in flasks containing 0.01% and 4.64 x 10E6 dpm in flasks containing 1.0% test material (1.11 and 0.53% of the initially applied activity, respectively). For the system containing 1 ppm 14C-labeled test material, the total activity recovered was 1.41% of the initial amount.
Test condition	: <p>Within 28 days, 71% of radioactivity from the positive control (glucose) was recovered as 14CO₂. Only trace amounts of radioactivity were recovered from negative controls.</p> <p>Microorganisms: Prior to testing, the microorganisms were acclimated to nonlabeled MC -680 (10 mg added on Day 1 and 100 mg added on Day 7) at 20 degrees C in the dark. The contents were mixed well and aerated every other day. At various intervals during acclimation, samples were taken and tested for microbial activity against 14C-labeled glucose. The final test medium (microbial medium) contained 50 ml of supernatant from acclimated microbes plus 10 ml of settled fresh sewage diluted to 500 ml with a minimum salt and vitamin solution. pH of this medium was adjusted to 7.1 at the beginning of the study. Medium used in experiments with 0.01 and 1.0% contained microorganisms that had been acclimated for 18 days, and medium used in experiments with 1 ppm contained microorganisms that had been acclimated for 46 days.</p>

System of testing: The extent of degradation was monitored by measuring

System of testing: The extent of degradation was monitored by measuring the amount of $^{14}\text{CO}_2$ liberated after addition of three different concentrations of ^{14}C -labeled test material (specific activity of 34 microcuries/mg) in microbial medium (1.0 ppm and 0.01% and 1.0%). Concentrations used were based on a preliminary study that showed that 10% test material was toxic, and that 1.0 % was not. Four replicates were prepared per test concentration. The test material was weighed directly into each 125-ml erlenmeyer flask containing 30 ml of medium and the acclimated bacteria (for 0.01 and 1.0%) or dissolved in ethylacetate (1.0 ppm) and transferred quantitatively. Two drops of Tween-80 surfactant were added to aid in dispersion of 1.0% test material. Two positive control flasks contained ^{14}C -labeled D-glucose and one negative control contained ^{14}C -labeled test material plus HgCl_2 (50 mg/l) in distilled water.

Each reaction vessel was equipped with a small center cup containing filter paper and 1.0 ml of 0.5 N KOH for absorption of the respired $^{14}\text{CO}_2$. Flasks were incubated at 19 to 23 degrees C in the dark under continuous shaking (85 cycles/min). Each flask was purged with a 70:30 O_2/N_2 mixture at least once per week. Liberation of $^{14}\text{CO}_2$ was monitored daily for the first 3 days, every 1 to 4 days up to 21 days, and then weekly thereafter. Tests with 0.01 and 1.0% test material were terminated after 211 days and with 1 ppm after 183 days.

The KOH solution from the center cup was transferred quantitatively with several small rinses to a scintillation counting vial. The filter paper was added to the same vial. The samples were counted in a scintillation counter for 10 minutes (and occasionally for 100 minutes). Efficiency of the scintillation counter was within 77 to 82%. Sensitivity was 7 dpm/min (or 92.7 picograms of test material) for a counting time of 100 min.

Test substance	:	Test material was a commercial product (MC-680).	
Reliability	:	(2) valid with restrictions. Purity of the test material was not verified.	(4)
18.09.2002			

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

Species	:	Cyprinus carpio (Fish, fresh water)
Exposure period	:	56 day at 25 degree C
Concentration	:	.3mg/l
BCF	:	= 8.6 - 27.1
Elimination	:	
Method	:	other
Year	:	1976
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	It is difficult to draw conclusions from the study due to the small number of fish tested, the large amount of variability and the relatively short duration. However, the data suggest that the material initially bioconcentrates in fish, but does not bioaccumulate to any large extent over time. None of the fish died, indicating that the 8-week lowest lethal concentration in carp is greater than 0.3 ppm.

The results of this study are summarized in the Hazardous Materials Databank for CAS No. 37853-59-1. In this document, the species used is incorrectly stated as orange-red-killifish.

As mentioned in the Hazardous Materials Databank, according to a classification scheme described by Franke C et al., Chemosphere 29:1501-

Result

- classification scheme described by Franke C et al., Chemosphere 29:1501-14, 1994, the BCF values calculated for 1,2-bis(2,4,6-tribromophenoxyethanol) suggest a low to moderate potential for bioconcentration in aquatic organisms.
- : The concentrations of test material found in fish exposed to 0.3 ppm for 2, 4, 6 or 8 weeks were 16.0 and 7.50 ppm, 2.76 and 7.47 ppm, 1.82 and 1.41 ppm, and 2.38 and 7.49 ppm, respectively. The concentrations of test material found in fish exposed to 0.03 ppm for 2, 4, 6 or 8 weeks were 0.474 and 0.492 ppm, 0.304 and 0.954 ppm, 0.677 and 0.757 ppm, and 1.13 and 0.661 ppm, respectively.

Test condition

- The bioconcentration factors (BCF) of the fish exposed to 0.3 ppm were 56.6 and 26.6, 10.3 and 27.9, 6.7 and 5.2 and 8.6 and 27.1 at 2, 4, 6, and 8 weeks, respectively. The concentration factors of the fish exposed to 0.03 ppm were 19.0 and 19.7, 11.9 and 37.4, 26.1 and 29.2, and 43.6 and 25.4 at 2, 4, 6, and 8 weeks, respectively.
- : Carp (avg weight and length of 30 g and 10 cm, respectively) were disinfected by being placed in an aqueous solution containing 30 g of CuSO₄ and 26 ml acetic acid in 60 liters of water for 30 seconds, followed by a 10 ppm solution of chlorotetracycline hydrochloride for 24 hours. They were acclimated for 14 days before being placed in test tanks 100 liter volume, glass). The flow rate and temperature of the test water were 576 liters per day and 25 +/- 2 degrees C, respectively.

Test material was solubilized in dimethyl sulfoxide and hydrogenated castor oil (22:20 w/w), sonicated for 10 minutes, and dissolved in water at a concentration of 500 mg/l. This material was supplied continuously to a mixing tank, where it was diluted and introduced into each test tank, so that concentrations of 0.03 and 0.3 ppm were delivered to the fish (8 per concentration). The exposure concentrations were 1/1000 and 1/10000 of the 48 hour LC₅₀ value previously determined for orange-red killifish. A test system also was set up in which 8 fish were exposed to water that did not contain test material (blank). The temperature of the water was 25 +/- 2 degrees C. Test water was dechlorinated city water (more details about the water were not provided), aerated so that the dissolved oxygen concentration was 7 ppm. Fish were fed with pelleted feed 2-3 times daily during the test. Feed did not contain chemicals that could interfere with the test.

Concentrations of test material in the water were measured 2, 4, 6, and 8 weeks after the beginning of the experiment. Two fish were removed at each of these time points, wiped lightly with gauze, and weighed. The fish were then cut into pieces, and homogenized in 50 ml of IN-potassium-ethyl alcohol solution for 2 hours. After distilled water (50 ml) was added, the homogenate was extracted with benzene (50 ml x 2). The benzene layer was then washed 3 times with distilled water (20 ml), and the aqueous layers were discarded. The benzene layer was filtered through anhydrous sodium sulfate, concentrated to about 5 ml, and purified using column chromatography (glass column, 10 mm diameter, 15 g Silica gel washed with HCl, benzene as effluent). The first 50 ml of the purified sample was subjected to gas chromatography [glass, 2 mm x 30 cm column containing Silicon DC200, 2%/Gas chrom Q (80/100 mesh), 235 degrees C, N₂ carrier gas, and ECD detector (63 Ni)].

The concentrations of test material in the exposure water were determined analytically by extracting the exposure water with benzene (50 ml x 2), filtering the benzene layer through anhydrous sodium sulfate, concentrating the samples to 50 ml, and subjecting the samples to gas chromatography (as described above).

The degree of accumulation, expressed by the bioconcentration factor (BCF), is calculated according to the following equation:

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Reliability : BCF = concentration of the test material in the fish body - mean concentration of the test material in the fish body at the start of and termination of the blank test/ mean concentration of the test material in the aquarium.
(2) valid with restrictions
The variability was large due to the small number (N=2) of fish assayed per time point. The duration of the experiment is too short to determine if the values at 0.3 ppm are starting to increase at 8 weeks.

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3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type : static
Species : Lepomis macrochirus (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring : no
LC50 : m = 1531
Method : other
Year : 1974
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : Although the values calculated were reported as TL50 values, it is obvious that these are LC50 values. TL50 values based on changes in behavior would be lower.

Result : The concentrations that caused mortality are higher than the normal water solubility of the material (without sonication).
 All fish exposed to 464 mg/l appeared normal. One fish exposed to 681 mg/l was dead at 24 hours, and one exposed to 1000 mg/l was dead at 72 hours. All other fish exposed to 681 or 1000 mg/l lived and had normal behavior. Fish exposed to 1470 mg/l appeared normal at 24 hours; however, all fish exposed to this concentration were staying on the bottom at 48 hours. At 72 hours, 4 of these fish were at the bottom, 3 were swimming side-up, 2 were lying on the bottom and 1 was dead. By 96 hours, 3 of the fish exposed to 1470 mg/l were swimming side-up, 4 were lying on the bottom and 2 were dead. Therefore, the total mortality rate at 1470 mg/l was 30%. All fish exposed to 2150 or 3160 mg/l had abnormal behavior at 24 hours. By 48 hours, 8 fish exposed to 2150 mg/l were dead. The two remaining fish continued to exhibit abnormal behavior at 72 hours, and were dead at 96 hours. All fish exposed to 3160 mg/l died by 72 hours (9 at 48 hours and 1 at 72 hours). All negative controls appeared normal at all evaluation times. Dissolved oxygen was greater than 5 mg/l and pH ranged from 6.5 to 7.5 during the test.

Test condition : The TL50 values (with confidence limits) at 24, 48 and 96 hours were > 3160 mg/l, 1977 (1734-2256) mg/l and 1531 (1317-1780) mg/l, respectively.
 Eighty bluegill fish (average weight of 1.4 g and length of 50 mm) were used. Fish were acclimated for 21 days prior to testing. During that period, mortality was < 5%. Fish used in the study were considered to be in excellent health, and were within 20% of the same weight and length. They were conditioned to the test water (deionized water containing 3 mg/l potassium chloride, 30 mg/l calcium sulfate, 30 mg/l magnesium sulfate and 48 mg/l sodium bicarbonate) for 4 days. The resistivity and pH were > = 1 million ohms and 7.0, respectively. No other information about test water composition was provided. Fish were not fed for 3 days prior to or during the test.

The test was conducted in 5 gallon glass jars kept at 18 +/- 0.5 degrees C. The jars were filled with 16 liters of aerated test water. Test material was suspended in test water by sonication and added to the jars at geometrically increasing concentrations (464, 681, 1000, 1470, 2150 and 3160 mg/l). Ten fish were exposed per concentration. The mass/volume ratio did not exceed 1.0 g fish/liter of test water. Two groups of 10 untreated fish each served as negative controls.

Behavior and mortalities were recorded at 24, 48, 72 and 96 hours. Medium was aerated again at 48 and 72 hours.

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	Dissolved oxygen and pH were monitored during the test. The toxic limit dose (TL50) value and confidence limits were calculated according to a modified method of Thompson (Bact Rev 11: 115-147, 1947).
Test substance	: The test material was a commercial product (Firemaster 680).
Reliability	: (2) valid with restrictions. The purity of the test material was not verified.
18.09.2002	(32)
Type	: static
Species	: other: Rainbow Trout
Exposure period	: 96 hour(s)
Unit	: mg/l
Analytical monitoring	: no
LC50	: m = 1410
Method	: other
Year	: 1974
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Remark	: Although the values calculated were reported as TL50 values, it is obvious that they are LC50 values. TL50 values based on changes in behavior would be lower.
Result	<p>The concentrations that caused mortality are higher than the normal water solubility of the material (without sonication).</p> <p>: All fish exposed to 464 mg/l appeared normal at all time points. All fish exposed to 681 mg/l survived and appeared normal (with the exception of 1 fish swimming side-up at 96 hours). One fish exposed to 1000 mg/l was found dead at 96 hours. All others exposed to this concentration appeared normal at all time points. Fish exposed to 1470 mg/l appeared normal at 24 hours; however, 5 and 3 were observed to be swimming side-up at 48 and 72 hours, respectively. By 96 hours, 4 of the fish exposed to 1470 mg/l were swimming side-up, 1 was lying on the bottom and had increased gill movement, and 5 were dead. Half of the fish exposed to 2150 mg/l were swimming or lying upside down on the bottom at 24 hours, and all were exhibiting similar behavior at 48 and 72 hours. All fish exposed to 2150 mg/l were dead at 96 hours. All fish exposed to 3160 mg/l had abnormal behavior at 24 hours, and were dead by 48 hours. All negative controls appeared normal at all evaluation times. Dissolved oxygen was greater than 5 mg/l and pH ranged from 7.0 to 7.5 during the test.</p> <p>The TL50 values (with confidence limits) at 24, 48 and 96 hours were > 3160 mg/l, 2612 (2491-2738) mg/l and 1410 (1215 -1637) mg/l, respectively.</p>
Test condition	<p>The Br content of the water containing 0, 464, 681, 1000, 1470, 2150 and 3160 mg/l was 1.0, 2.0, 2.5, 15.5, 38.4, 10.6 and 276.0 ppm at 1 hour (respectively) and 0.2, 3.3, 1.1, 2.8, 5.4, 2.5 and 8.9 ppm at 96 hours.</p> <p>: Eighty rainbow trout (average weight of 1.9 g and length of 45 mm) were used. Fish were acclimated for 21 days prior to testing. There were no deaths during the 8-day period immediately preceding the test. Fish used in the study were considered to be in excellent health, and were within 20% of the same weight and length. They were conditioned to the test water (deionized water containing 3 mg/l potassium chloride, 30 mg/l calcium sulfate, 30 mg/l magnesium sulfate and 48 mg/l sodium bicarbonate) for 4 days. The resistivity and pH were > = 1 million ohms and 6.2, respectively. No other information about test water composition was given. Fish were not fed for 3 days prior to or during the test.</p> <p>The test was conducted in 5 gallon glass jars kept at 13 +/- 0.5 degrees C. The jars were filled with 16 liters of aerated test water. Test material was suspended in test water by sonication and added to the jars at geometrically increasing concentrations (464, 681, 1000, 1470, 2150 and 3160 mg/l). Ten fish were exposed per concentration. The mass/volume ratio did not exceed 1.5 g fish/liter of test water. Two groups of 10</p>

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ratio did not exceed 1.19 g fish/liter of test water. Two groups of 10 untreated fish each served as negative controls.

Behavior and mortalities were recorded at 24, 48, 72 and 96 hours. Medium was aerated again at 48 hours. Dissolved oxygen and pH were monitored during the test. The toxic limit dose (TL50) value and confidence limits were calculated according to a modified method of Thompson (Bact Rev 11: 115-147, 1947). The concentration of bromine was measured in water samples collected from test vessels at 1 and 96 hours.

Test substance : The test material was a commercial product (Firemaster 680).
Reliability : (2) valid with restrictions. The purity of the test material was not verified.
18.09.2002 (33)

Type : static
Species : *Oryzias latipes* (Fish, fresh water)
Exposure period : 48 hour(s)
Unit : mg/l
Analytical monitoring : no
LC50 : $m = 230$
Method : other
Year : 1976
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : Results other than the LC50 value were not reported. This was a preliminary experiment to determine the concentration of test material to be used in a bioaccumulation study. The LC50 value is higher than the normal water solubility of the material (without solubilization).

Test condition : Test material was solubilized in dimethyl sulfoxide and hydrogenated castor oil (22:20 w/w), sonicated for 10 minutes, and dissolved in water at a concentration of 500 mg/l. This material was supplied continuously to a mixing tank, where it was diluted with 100 times the volume of water and introduced into each test tank. The temperature of the water was 25 +/- 2 degrees C. Test water was fresh underground or dechlorinated city water (more details were not provided) aerated so that the dissolved oxygen concentration was 7 ppm. Mature orange-red killifish (avg. weight 0.2 g, number not stated) were exposed to various concentrations of test material for 48 hours and mortalities were recorded.
Reliability : (2) valid with restrictions. The purity of the test material is unknown.
18.09.2002 (6)

Type : other
Species : other: not specified
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring :
LC50 : $c = 43.509$
Method : other
Year : 2002
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Method : EPIWIN ECOSAR (v0.99g) was used to estimate acute toxicity to fish. Inputs to program for the test substance were CAS No., measured melting point of 224 degrees C, measured water solubility of 0.2 mg/l at 25 degrees C, and a measured Log Pow of 3.14. Other inputs were standard defaults.
Remark : The ECOSAR estimated 14 day LC50 is 94.4 mg/l.
Reliability : (2) valid with restrictions. Data were obtained by modeling.
18.09.2002 (11)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type : other
Species : Daphnia magna (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
Analytical monitoring :
LC50 : c = 50.43
Method : other
Year : 2002
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Method : Acute Daphnid LC50 was estimated by EPIWIN ECOSAR (v0.99g). Model inputs used were CAS No. of test substance, measured water solubility of 0.2 mg/l at 25 degrees C, measured melting point of 224 degrees C, and measured Log Pow of 3.14. All other inputs were standard defaults.
Remark : The ECOSAR estimated 16 day EC50 is 4.25 mg/l.
Reliability : (2) valid with restrictions. Data were obtained by modeling.
 18.09.2002 (11)

Type : other
Species : other: Mysid shrimp
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring :
LC50 : c = 5.573
Method : other
Year : 2002
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Method : Acute Mysid Shrimp LC50 was estimated by EPIWIN ECOSAR (v0.99g). Model inputs used were CAS No. of test substance, measured water solubility of 0.2 mg/l at 25 degrees C, measured melting point of 224 degrees C, and measured Log Pow of 3.14. All other inputs were standard defaults.
Reliability : (2) valid with restrictions. Data were obtained by modeling.
 18.09.2002 (11)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species : other algae: green
Endpoint : other: not mentioned
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring :
EC50 : c = 33.66
Method : other
Year : 2002
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Method : EPIWIN ECOSAR (v0.99g) was used to estimate acute toxicity to algae. Inputs to the model were CAS No. of test substance, measured melting point of 224 degrees C, measured water solubility of 0.2 mg/l, and measured Log Pow of 3.14. All other inputs were standard defaults.
Reliability : (2) valid with restrictions. Data were obtained by modeling.
 18.09.2002 (11)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO OTHER NON-MAMM. TERRESTRIAL SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.1.1 ACUTE ORAL TOXICITY

Type	: LD50
Species	: rat
Strain	: other: Spartan
Sex	: male/female
Number of animals	: 20
Vehicle	: other: 0.5% Methocel
Value	: > 10000 mg/kg bw
Method	: other
Year	: 1974
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Result	: None of the animals died during the study. All rats exhibited normal body weight gains. Upon necropsy, 2 females receiving the micronized material exhibited hydrometra, which was mentioned by the authors as being "not an uncommon finding in control rats of this age and sex". Therefore, these changes were not attributed to be due to test material administration. There was no mention of any adverse clinical signs.
Test condition	: The acute oral LD50 value of either micronized or non-micronized Firemaster 680 was greater than 10,000 mg/kg. : Ten rats/sex (212 to 250 grams) were used in the study. They were fasted overnight before treatment with either non-micronized or micronized test material (5/sex/group) by gavage. Test material was suspended in 0.5% Methocel and administered at volume of 30 ml/kg. Food and water were available ad libitum after treatment. All rats were observed for mortality for 14 days. Body weights were measured initially and at 14 days. All rats that received the micronized material were necropsied and subjected to a gross pathological examination after 14 days.
Test substance	: The test material was a commercial product (Firemaster 680). Two formulations were tested; one micronized and another that was not micronized.
Conclusion	: The test material was not considered to be a toxic material by the oral route of administration.
Reliability	: (2) valid with restrictions. The purity of the test material was not stated.
18.09.2002	(40)
Type	: LD50
Species	: rat
Strain	: Sprague-Dawley
Sex	: male
Number of animals	: 12
Vehicle	: other: corn oil
Value	: > 10000 mg/kg bw
Method	: other
Year	: 1972
GLP	: no data
Test substance	: other TS
Result	: There was no mention of any clinical signs. No animals died during the study. LA-680 has an estimated oral LD50 to rats in excess of 10 grams per kilogram body weight.
Test condition	: Fasted (24 hours), adult albino male rats (6/group; 150 - 250 g) were given a single dose of 5 or 10 gm/kg body weight test material in corn oil by stomach tube and observed for 2 weeks. They were allowed free access to food and water after dosing.
Test substance	: The test material was referred to as "Sample LA-680" of an experimental flame retardant.
Reliability	: (3) invalid. No documentation is given proving that the test substance

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(2)

Type : LD50
Species : dog
Strain : Beagle
Sex : male/female
Number of animals : 4
Vehicle : other: 0.5% Methocel
Value : > 10000 mg/kg bw
Method : other
Year : 1974
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Result : None of the animals died. According to the authors "no significant pharmacodynamic signs were observed in any of the animals." White discolored feces were found in one female at 4.5 hours, all four animals at 24 hours, one male and two females at 48 hours, and one female at both 72 hours and 8 days. Soft feces were noted in one female at 24 hours. Lacrimation was found in one male at 24 hours, and one male and one female at 48 hours. No adverse effects on body weight were found. Two males and one female maintained their weights, and one female gained weight.
Test condition : Two dogs/sex (7.55 to 11.50 kg) were used in the study. They were fasted overnight before treatment with test material (10 g/kg) by gavage. Test material was suspended in 0.5% Methocel. Treatment was followed by rinsing with 20 ml 0.5% Methocel. Food and water were available ad libitum after treatment. Each dog was observed for clinical signs and mortality from 0 to 5 hours, at 24 hours, and daily thereafter for a total of 14 days. Body weights were measured initially and at 14 days.
Test substance : The test material was a commercial product (Firemaster 680).
Reliability : (2) valid with restrictions. The purity of the test material was not verified.
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5.1.2 ACUTE INHALATION TOXICITY

Type : LC50
Species : rat
Strain : other: Spartan
Sex : male/female
Number of animals : 10
Vehicle :
Exposure time : 4 hour(s)
Value : > 36.68 mg/l
Method : other
Year : 1974
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : It was noted that higher concentrations could not be tested due to the physical properties of the material. Since the average particle size was not determined, the actual amount of respirable material is unknown.

The gray foci in the lungs were not considered by the authors to be related to test material since they are commonly found in rats of the same age and stain.
Result : No rats died during exposure or the 14 day observation period. Signs noted during the exposure included eye squint, erythema, slight dyspnea, slight bradypnea, salivation, nasal porphyrin discharge, and increased, then decreased motor activity. At 24 hours and for the duration of the 14 day study period, all rats appeared normal except one (unknown sex) that exhibited nasal porphyrin discharge on Days 7 and 8. All rats exhibited

	exhibited nasal porphyrin discharge on Days 7 and 8. All rats exhibited normal body weight gains. The authors stated that there were no compound-related necropsy findings. Three rats exhibited gray foci in the lungs.
	Based on the results, the 4-hr LC50 value in albino rats for inhalation of micronized Firemaster is greater than 36.68 mg/l.
Test condition	: The test material was a commercial product (Firemaster 680). The material was micronized by the supplier.
Test substance	: Five male and 5 female rats (200 - 244 g) were exposed for 4 hours to a dust of the test material in sealed 59.1 liter glass chambers (2-3 rats per chamber) at a calculated atmospheric concentration of 36.68 mg/l. Addition of test material to the chamber atmosphere was controlled by a Wright Dust Feeder. Dried and filtered air was passed through the mechanism and directly into the chamber. Airflow (rate not stated) was regulated with a flowmeter. The rats were observed continuously during exposure for changes in behavior and/or appearance and up to 14 days after exposure for toxic signs. Animals were weighed before exposure and 14 days after exposure. All rats were euthanized 14 days after exposure and subjected to a gross necropsy.
Reliability	: (2) valid with restrictions. The average particle size and the purity of the test material were not mentioned.
18.09.2002	(31)
Type	: LC50
Species	: rat
Strain	: other: Charles River
Sex	: male/female
Number of animals	: 10
Vehicle	:
Exposure time	: 4 hour(s)
Value	: > 13.08 mg/l
Method	: other
Year	: 1976
GLP	: no data
Test substance	: other TS: vapor of Granulated Firemaster 680 containing Television rings manufactured by Xolox Corp, heated to 135 degrees C.
Remark	: The particulate matter concentration was higher at the beginning of the test (0.973 mg/l air) than it was at 1 hour and subsequent time points (0.033 - 0.047 mg/l air), indicating that the chamber conditions kept most of the material vaporized.
Result	: No animals died during the exposure or the 14 day post- observation period. Average 2 -week body weight gains (57-32 g) were within normal limits. Necropsies did not reveal any gross pathologic alterations that could be attributed to test material.
	The average particulate matter concentration was 0.228 mg/l air and the nominal concentration of test material was 13.08 mg/l air.
Test substance	: Five male and 5 female rats were exposed for 4 hours to the vapor generated by passing a stream of clean, dry air over the test material (Granulated FM 680 containing Television rings manufactured by Xolox Corp) heated to 135 degrees C. Particulate matter samples, analytical samples for tribromophenol and the nominal concentration of test material were calculated. The size, atmospheric pressure, temperature and airflow of the chamber were 80 liters, 29.96 inches Hg, 28 degrees C and 2.0 l/min, respectively.
	Animals were weighed before exposure and after a 14-day observation period. Animals were euthanized and necropsied at the end of the observation period.
Conclusion	: The acute LC50 for the vapor of the test material was greater than 13.08 mg/l air (nominal concentration).

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Reliability 18.09.2002	:	(2) valid with restrictions. Purity of the starting material was not given.	(20)
Type	:	LC50	
Species	:	rat	
Strain	:	other: Spartan	
Sex	:	male/female	
Number of animals	:	10	
Vehicle	:		
Exposure time	:	4 hour(s)	
Method	:	other	
Year	:	1975	
GLP	:	no data	
Test substance	:	other TS: pyrolysis product of ABS Resin/FM680/Sb2O3, lot #607-43-G.	
Remark	:	A similar study was conducted using ABS Resin/Sb2O3 that did not contain FM680 (see next record). There are no significant differences between the results of the two studies, indicating that pyrolysis products formed from resin containing FM680 was no more toxic by inhalation than resin that did not contain FM680.	
Result	:	No deaths occurred during the 4 hour exposure period or during the subsequent 14-day period of observation. Signs observed during the exposure included decreased motor activity, eye squint, slight dyspnea, and ocular porphyrin discharge. These symptoms resolved over 48 hours through 14 days. The number of rats affected was not stated. One or two rats exhibited soft stool at 48 hours and 8, 10, 12, 13, and 14 days. One rat had respiratory congestion at 8, 9, 12 and 13 days, and another had ocular lesions from 48 hours through 7 days. All rats had normal weight gains. At necropsy, 2/10 rats had scattered gray foci or congestion in the lungs.	
		The weight loss of compound in the flask after pyrolysis at 4 hours was 2.45 %. The temperature of the oil bath, test material and atmosphere of the exposure chamber were 485-500, 450-464 and 68-69 degrees F throughout the exposure, respectively.	
Test substance	:	Five rats of each sex (203-239 g) were exposed to an atmosphere containing pyrolysis products of the test material for 4 hours in sealed 59.1 liter glass chambers (2-3 per chamber). The chamber atmosphere was prepared by passing an airflow of 10 lpm through a 500 ml, 3-necked flask containing 100.02 g of ABS Resin/FM 680/Sb2O3. The flask was immersed in an oil bath. Airflow through the flask was not initiated until the temperature of the test compound reached at least 450 degrees F. The temperatures of the oil bath, test compound and atmosphere were monitored throughout the exposure. The flask containing the test material was weighed before and after the exposure to determine the percent weight loss.	
		Rats were observed for behavior and appearance during the 40-hour exposure and for signs of toxicity for 14 days, after which they were euthanized and necropsied.	
Reliability 18.09.2002	:	(2) valid with restrictions. The tested product contains antimony.	(36)
Type	:	LC50	
Species	:	rat	
Strain	:	other: Spartan	
Sex	:	male/female	
Number of animals	:	10	
Vehicle	:		
Exposure time	:	4 hour(s)	
Method	:	other	
Year	:	1975	
GLP	:	no data	

Test substance	: other TS: pyrolysis product of ABS resin/Sb2O3, lot #607-43-D.
Remark	: It was not possible to determine the amount of material that was pyrolyzed because the flask containing test material shattered upon cooling.
Result	: No deaths occurred during the 4 hour exposure period or during the subsequent 14 day period of observation. Signs observed during the exposure included decreased motor activity, eye squint, slight dyspnea, ocular porphyrin discharge and lacrimation. The number of affected animals was not stated. At 24, 48 and 72 hours, respiratory congestion and drying of the corneal surface were observed (number of animals not stated). One rat exhibited corneal opacity at 48 hours. From 4 through 7 days, drying of the corneal surface, corneal opacity, corneal lesions and soft stool were observed in several rats (the number was not stated). Soft stool was observed in one or two rats on Days 8, 9, 13 and 14. At necropsy, 2 of the 10 rats exhibited petechiation of the lungs.
Test substance	<p>The temperature of the oil bath, test material and atmosphere of the exposure chamber were 490 -495, 460-465 and 67-70 degrees F throughout the exposure, respectively.</p> <p>: Five rats of each sex (238 -278 g) were exposed to an atmosphere containing pyrolysis products of the test material for 4 hours in sealed 59.1 liter glass chambers (2-3 per chamber). The chamber atmosphere was prepared by passing an airflow of 10 lpm through a 500 ml 3 necked flask containing ABS Resin/Sb2O3. The flask was immersed in an oil bath. Airflow through the flask was not initiated until the temperature of the test compound reached at least 450 degrees F. The temperatures of the oil bath, test compound and atmosphere were monitored throughout the exposure. The flask containing the test material was to be weighed before and after the exposure to determine the percent weight loss.</p> <p>Rats were observed for behavior and appearance during the 40-hour exposure and for signs of toxicity for 14 days, after which they were euthanized and necropsied.</p>
Reliability	: (2) valid with restrictions The reliability code listed is for the test material, which does not contain CAS No. 37853-59-1. The reliability code for CAS No. 37853-59-1 is 3 (invalid). The study is included for comparative purposes.

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(35)

5.1.3 ACUTE DERMAL TOXICITY

Type	: LD50
Species	: rabbit
Strain	: other: albino
Sex	: male
Number of animals	: 2
Vehicle	:
Value	: > 10000 mg/kg bw
Method	: other
Year	: 1973
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Result	: Neither animal died during the study. There was no mention of any clinical signs of toxicity.
Test condition	: Two adult male rabbits (1444 and 1593 g) were administered a dose of 10 g/kg of test material under a sleeve of rubber snugly fastened about the clipped trunk. The animals were immobilized for a 24 hour period immediately following treatment. At the end of exposure the sleeves were removed and the animals observed for 2 weeks. Animals were weighed on Days 7 and 14.
Test substance	: The test material was a commercial product (Firemaster 680).

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Conclusion	: The acute dermal LD50 value is greater than 10 g/kg body weight.
Reliability	: (2) valid with restrictions. The purity of the test material was not verified.
18.09.2002	(30)
Type	: LD50
Species	: rabbit
Strain	: other: albino
Sex	: male
Number of animals	: 2
Vehicle	:
Value	: > 2000 mg/kg bw
Method	: other
Year	: 1972
GLP	: no data
Test substance	: other TS
Result	: Neither animal died during the study. There was no mention of any adverse clinical signs. Animals gained weight over the recovery period.
Test condition	: Two adult male rabbits (1914 and 2491 g) were administered a dose of 2 gm/kg of test material under a sleeve of rubber snugly fastened about the clipped trunk. The animals were immobilized for a 24 hour period immediately following treatment. At the end of exposure the sleeves were removed and the animals observed for 2 weeks. Animals were weighed 7 and 14 days after treatment.
Test substance	: The test material was referred to as "Sample LA-680" of an experimental flame retardant.
Conclusion	: The acute dermal LD50 value for the test material is greater than 2 g/kg body weight.
Reliability	: (3) invalid. No documentation is given proving that the test substance contained CAS No. 37853-59-1.
18.09.2002	(1)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

Species	: rabbit
Concentration	: undiluted
Exposure	: Semiocclusive
Exposure time	: 24 hour(s)
Number of animals	: 6
PDII	: 0
Result	: not irritating
EC classification	: not irritating
Method	: other
Year	: 1972
GLP	: no data
Test substance	: other TS
Result	: All readings were negative; therefore the primary skin irritation score was 0.
Test condition	: The test material (0.5 g) was applied to each of two clipped areas on the backs and flanks of 6 albino rabbits. One site was abraded and one was intact. The sites were covered with gauze patches moistened with water and taped in place. The animals were fitted with collars for 24 hours, after which coverings were removed and skin was graded on a scale of 0-4 for 1) erythema and eschar formation and 2) edema. A second reading was taken at 72 hours. The average of the scores at 24 and 72 hours was used to determine the primary irritation score.
Test substance	: The test material was referred to as "Sample LA-680" of an experimental flame retardant. Purity was not given

5. Toxicity

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Reliability	: (3) invalid. No documentation is given proving that the test substance contained CAS No. 37853-59-1.	
17.09.2002		(1)
Species	: rabbit	
Concentration	: undiluted	
Exposure	: Occlusive	
Exposure time	: 24 hour(s)	
Number of animals	: 6	
PDII	: 1.9	
Result	: slightly irritating	
EC classification	: irritating	
Method	: other: Draize	
Year	: 1976	
GLP	: no data	
Test substance	: other TS: Mother liquor 680 process, code #7-29-76-B.	
Result	: All edema scores were 0. The average erythema score for both intact and abraded sites was 2.5 at 24 hours and 1.3 at 72 hours. The primary irritation score was 1.9/8, which was considered to be indicative of mild irritation.	
Test condition	: Two sites (one intact, one abraded) were prepared on the clipped backs of each of 6 rabbits. 0.5 ml of the test material was applied to each test site and occluded with gauze patches secured with masking tape. The trunk of each animal was wrapped with impervious plastic sheeting. At the end of 24 hours, the wrappings, patches and residual test material were removed and the sites scored immediately and at 72 hours for erythema and edema on a graded score of 0 to 4. The mean erythema and edema scores for the intact and abraded sites at 24 and 72 hours were added and divided by 4 to obtain the mean primary irritation score.	
Test substance	: The test material contained 67% 1,2-propanediol, 17.5% sodium bromide, 6.2% water, 2.9% ethers of 1,2-propanediol and 1-bromo-2(2,4,6-tribromophenoxy)ethane, 2.5% sodium salt of 2,4,6-tribromophenol, 1.9% 2(2,3,6-tribromophenoxy)ethanol, 1.1% vinyl tribromophenolate, 0.2% phenol, 0.2% tribromophenol, < 0.1% 1-bromo-2(2,4,6-tribromophenoxy)ethane and < 0.01% isopropanol. The pH was 8.1.	
Reliability	: (2) valid with restrictions The reliability rating listed is for the mother liquor. The reliability rating of the study for CAS No. 37853-59-1 is 3 (invalid) since the test material did not contain any of it. However, the study is included because it was performed on the materials used to make CAS No. 37853-59-1.	
18.09.2002		(5)

5.2.2 EYE IRRITATION

Species	: rabbit
Concentration	: undiluted
Dose	: .1 g
Exposure Time	:
Comment	: not rinsed
Number of animals	: 6
Result	: not irritating
EC classification	: not irritating
Method	: other
Year	: 1972
GLP	: no data
Test substance	: other TS
Result	: All readings for the cornea (opacity, area), iris and conjunctivae (redness, chemosis, discharge) were given scores of 0.
Test condition	: Test material (0.1 g) was instilled into one eye of each of 6 adult New

5. Toxicity

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Zealand White rabbits that had been fitted with collars. The other eye of each rabbit served as an untreated control. The reaction was scored according to a scale (details were not provided) for damage to the cornea, iris and bulbar and palpebral conjunctivae at 24, 48 and 72 hours after instillation. Any residue was flushed from the eyes each time they were scored.

Test substance : The test material was referred to as "Sample LA-680" of an experimental flame retardant

Reliability : (3) invalid. No documentation is given proving that the test substance contained CAS No. 37853-59-1.

18.09.2002 (1)

5.3 SENSITIZATION

Type : other: modified Draize multiple insult test

Species : human

Concentration : Induction undiluted occlusive epicutaneous
Challenge undiluted occlusive epicutaneous

Number of animals : 45

Vehicle :

Result : not sensitizing

Classification : not sensitizing

Method : other

Year : 1975

GLP : no data

Test substance : as prescribed by 1.1 - 1.4

Result : Forty five of the 50 subjects completed the study. No evidence of irritation was observed during the sensitizing phase of the study. One subject had a "very questionable reaction" and another a "low level reaction" 72 hours after challenge. All others tested negative. Following the challenge dose, one subject had a delayed response that appeared to be irritation. It is not known if this subject was one of the subjects referred to previously. A second challenge dose given to this subject gave completely negative results, indicating that contact sensitization had not occurred.

Test condition : Fifty healthy male human volunteers were used in the study. The races of the men were white (53.3%), black (33.3%), Mexican (8.8%), or American Indian (4.2%). Their average age was 31.4 years, with a range of 22-52 years. The average weight was 171.6 lbs, with a range of 126-235 lbs. The average height was 5'9", with a range of 5'6"-6'4".

Test material was applied under occlusion (as an aqueous paste) to the skin of each volunteer. The test material was applied fresh every other day for a total of 10 applications. A new site was used for each application. There was a rest period of 10-14 days after the last application. The subjects were then challenged with test material in a manner identical to that used for the sensitizing doses (except that challenge doses were applied at a different site than sensitizing doses). The challenge site was examined at 48 and 72 hours. If a result was questionable, the subject was retested one week later.

Test substance : The test material was a commercial product (Firemaster 680, lot 761-7).

Conclusion : The test material produced no significant irritation and gave no evidence of contact sensitization in the 45 subjects who completed the study.

Reliability : (2) valid with restrictions
The purity of the test material was not verified.

18.09.2002 (34)

Type : Buehler Test

Species : guinea pig

Concentration : Induction undiluted occlusive epicutaneous

	Challenge undiluted occlusive epicutaneous
	Challenge 10 % occlusive epicutaneous
Number of animals	: 14
Vehicle	: water
Result	: not sensitizing
Classification	: not sensitizing
Method	: other
Year	: 1976
GLP	: no data
Test substance	: other TS
Result	: Most of the animals exhibited minimal to slight erythema after 4 applications. This resolved by the 9th application in most animals. Similar, minimal reactions were noted in 4-6 control and treated animals 24 and 48 hours after challenge with undiluted material. No responses were noted in animals challenged with 10.0% test material in aqueous solution.
Test condition	: Webril pads containing 0.5 ml of undiluted test material were applied near the midline of the shaved back of 10 animals. The pad was occluded with a standard size coverlet and each animal was restrained for 5 hours. This procedure was repeated for a total of 9 applications (presumed daily). Animals were graded after each application (with the exception of application 6). Two weeks after the last exposure, test animals and 4 control animals that had not been treated were challenged with a patch treated with undiluted material. Two days later, they were challenged with another patch treated with a 10% (w/v) aqueous solution of test material. The application sites were graded for irritation 24 and 48 hours after challenge. Any reaction among the test animals at challenge that was greater than that seen after the initial insult or greater than that noted among the control animals at challenge was considered evidence of sensitization.
Test substance	: The test material contained 67% 1,2-propanediol, 17.5% sodium bromide, 6.2% water, 2.9% ethers of 1,2-propanediol and 1-bromo-2(2,4,6-tribromophenoxy)ethane, 2.5% sodium salt of 2,4,6-tribromophenol, 1.9% 2(2,3,6-tribromophenoxy)ethanol, 1.1% vinyl tribromophenate, 0.2% phenol, 0.2% tribromophenol, < 0.1% 1-bromo-2(2,4,6-tribromophenoxy)ethane and < 0.01% isopropanol. The pH was 8.1.
Conclusion	: The test material was not a sensitizer, but caused minimal to slight skin irritation.
Reliability	: (2) valid with restrictions The listed reliability rating is for the mother liquor. The reliability of this study for CAS No. 37853-59-1 is 3 (invalid), since the test material did not contain any of it. However, the study is included because it was performed on the materials used to make CAS No. 37853-59-1.
18.09.2002	(8)

5.4 REPEATED DOSE TOXICITY

Species	: rat
Sex	: male/female
Strain	: other:Charles River
Route of admin.	: oral feed
Exposure period	: 106 days
Frequency of treatment	: daily in feed
Post obs. period	: none
Doses	: 0.1, 1.0 and 10.0% in diet
Control group	: yes, concurrent no treatment
NOAEL	: = 1 %
LOAEL	: = 10 %
Method	: other
Year	: 1977

GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Remark	<p>: Concentrations of test material in diets were not verified analytically. It is assumed (but not stated) that control animals were pair fed. Based on average food consumption and body weight data, the .01, 1.0 and 10% doses in mg/kg were 71.7, 729 and 8329 for males and 84.6, 874 and 9364 for females, respectively.</p> <p>The test was originally planned to be a 90-day test. Animals were maintained on test diet for an additional 16 days due to an unavoidable scheduling conflict with the necropsy.</p> <p>The results of the study may be influenced by the presence of pneumonia. Histopathological changes other than focal or multifocal hypertrophy of hepatocytes were considered by study personnel to be "lesions of naturally occurring diseases".</p> <p>Although there were changes in some hematological variables in treated animals compared to study controls, the authors stated that the values in treated animals were within the range of historical controls. Therefore, they were not considered to be significant. None of the hematological or clinical chemistry changes were considered to be related to treatment by test personnel.</p>
Result	<p>: Fourteen animals (2 male and 3 female controls, 1 female treated with 0.1%, 2 females treated with 1.0%, and 6 females treated with 10.0%) died during the study. Eleven of the deaths occurred immediately after collection of blood on either days 40 or 84; the cause of death for the other 3 rats was not determined.</p> <p>Body weights, weight gains and food consumption of treated animals were similar to controls. No clinical signs of toxicity were noted. Compared to controls, females treated with 1.0% and 10% had lower average erythrocyte counts and hematocrit at 84 days. Females treated with 1.0% or 10% had lower total leukocyte counts at 84 and 40 days, respectively. Males treated with 10% had lower total leukocyte counts at 84 days and a lower hematocrit at 40 days. Males and females treated with 10% had lower hemoglobin at 40 days. Slight increases were noted in the serum alkaline phosphatase activity among males fed 10% diets at 40 and 84 days of testing. Fasting blood glucose in high dose males and females was lower than control at 40 and 84 days, respectively. There were no significant differences in any urine parameter between controls and treated animals.</p> <p>Gross pathologic findings were similar among control and treated animals. The weight of kidneys relative to body weight was higher in mid-dose males than controls (0.7877 vs. 0.7077). Absolute and relative weights of other organs were similar between controls and treated animals. Histopathologic examination revealed hepatic changes among most animals in the 10% group (10/10 males and 6/10 females). The lesions consisted of either focal or multifocal enlargement of hepatocytes located within the centrilobular to midzonal regions of affected liver lobules. Nine high dose males also exhibited hepatic focal sinusoidal or portal lymphoid infiltrations (compared to 3 controls). Four high dose females had focal extramedullary hematopoiesis (portal and sinusoidal) compared to one control. The severity of these liver lesions was graded as minimal in all animals. No significant histological changes were evident in the livers of animals fed either 0.1 or 1.0%.</p> <p>High dose male and female animals also had an increased incidence of mild unilateral or bilateral hypervolemia of the adrenal gland (5 treated males vs. 2 controls and 3 treated females vs. 0 controls). High dose males also had an increased incidence of focal cytoplasmic vacuolization of basophils in the pituitary (6 treated vs. 3 controls) and high dose females</p>

Test condition

basophils in the pituitary (6 treated vs. 3 controls) and high dose females had an increased incidence of focal hyperplasia in the pituitary (2 treated vs. 0 controls). High dose males also had a higher incidence of foci of epidermal acanthosis of the skin (3 treated vs. 1 control). High dose females exhibited an increased incidence of focal interstitial lymphoid infiltrations in the pancreas (3 treated vs. 1 control) and hydrometra of the uterus (3 treated vs. 0 controls). All lesions were graded as minimal to mild. None of these changes were considered by test personnel to be related to treatment.

Nine out of 10 control and 10/10 treated males and all females exhibited minimal to mild chronic murine pneumonia and mild-moderate chronic tracheitis. The majority of control and high dose males and females also had aggregates of alveolar macrophages in the lungs.

- : One hundred-twenty rats (60/sex; 21 days of age) were acclimated for 8 days and randomly divided into 1 control and 3 test groups (15/sex/group). The 3 test groups received 0.1, 1.0 and 10.0% test material in the diet for 106 days. Test diets were prepared by blending the appropriate amount of test material with standard rat ration in a high-speed blender. Each rat was given an amount of diet sufficient for 1 week's ad libitum feeding. Rations were checked daily to ensure that they were sufficient. Fresh diets were prepared weekly. Control animals were given basal diet without test material.

Animals were weighed on the first day of testing and weekly thereafter. Food consumption data were collected weekly from 5 individual rats/sex/group. Rats were observed daily for death or abnormal reactions. Fasted blood and urine samples were collected from 10 rats/sex from the control and high dose groups after 40 days of treatment and from all groups after 84 days. Blood samples were analyzed for total and differential leukocyte count, erythrocyte count, hemoglobin, hematocrit, glucose, serum alkaline phosphatase, serum glutamic pyruvic transaminase, and blood urea nitrogen. Urine samples were analyzed for glucose, albumin, pH, specific gravity and microscopic elements (eg. crystals).

After being on test for 106 days, surviving rats were euthanized and necropsied. Animals that died during the study were also necropsied if autolysis did not occur. The weights of the brain, gonads, heart, liver, kidneys, and spleen of each rat were recorded. The adrenals, aorta (thoracic), brain, cecum, colon, esophagus, eyes (with optic nerves), gonads (testes, prostate, prostatic urethra and epididymis in males and ovaries and uterus in females), heart, kidneys, liver, lung, lymph nodes (cervical, mesenteric), skeletal muscle, pancreas, peripheral nerve (sciatic), pituitary, prostate, salivary gland (submaxillary, sublingual, parotid), small intestine, spinal cord, spleen, sternum (bone marrow), stomach, thyroid, trachea and urinary bladder of control and high dose animals were examined histologically. Sections of liver from 10 rats/sex of the other test groups also were examined.

Body weight, hematologic, clinical chemical, and organ weight data were analyzed by one way analysis of variance. Significant effects were further analyzed by either the Tukey's (for equal population size) or Scheffe's (for unequal population size) multiple comparison test. Organ to body weight and organ to brain weight ratios were analyzed by the Kruskal-Wallis Strategic Test. Significant effects were further analyzed by the Kruskal-Wallis Multiple Comparison Test. Differences from control were designated as being significant at either the $p < 0.05$ or $p < 0.01$ level. Historical control data were consulted in some instances.

Test substance
Reliability
18.09.2002

- : The test material was a commercial product (Firemaster 680).
: (2) valid with restrictions. The purity of the test material was not verified.

(24)

5. Toxicity

Id 37853-59-1

Date 18.09.2002

Species : rat
Sex : male
Strain : no data
Route of admin. : oral feed
Exposure period : 28 day
Frequency of treatment : daily
Post obs. period : 6 weeks
Doses : 100 and 1000 ppm in diet
Control group : yes, concurrent no treatment
NOAEL : < 100 ppm
LOAEL : = 100 ppm
Method : other
Year : 1972
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : The authors remarked that the toxicological significance of the decreased organ weights in the treated animals is unclear since body weight gains were only slightly depressed and there were no corresponding changes in histopathology or clinical chemistry. Additional groups of animals (rerun animals) also did not have reduced weight gains. The fact that body weight gains and food consumption recovered in treated animals after cessation of treatment suggested to the authors that these effects resulted from problems with palatability, or at most, minimal, reversible toxicity.

Based on average food consumption and body weight, the doses in mg/kg were calculated by the summary writer to be 13.7 and 138.5 mg/kg/day. Food consumption of the rerun animals was not calculated; therefore the mg/kg dose for these animals could not be calculated.

Result : There were no deaths. Treated animals gained slightly less weight than control animals. Those treated with 100 ppm had normal weight gains for the first two weeks. At weeks 3 and 4 they gained an average of 40 g (compared to 47 in controls) and 31 g (compared to 40 g in controls). For animals treated with 1000 ppm, the reduced weight gain was most evident for week 1 (20 g vs. 31 g in controls). After this time, average weight gain in the high dose groups was similar to controls. Final weight gain in the control, low and high dose groups was 161, 141 and 150 g, respectively. For the rerun animals, average body weight gains of treated animals were similar to those of controls. Feed efficiency (grams feed consumed/grams gained) of high dose animals was slightly greater than control at one (3.8 vs. 2.5) and 3 weeks (3.5 vs. 2.9) and of low dose animals was greater than control at 3 (3.3 vs. 2.9) and 4 (4.2 vs. 3.5) weeks. Overall feed efficiency in the low (3.2) and high (3.1) dose groups was only slightly higher than control (2.9). Body weight gains and food consumption recovered during the withdrawal period in those animals that had reductions in these variables during the test feeding period.

White blood cell counts in mid and high dose animals were slightly higher than control at 7 days, but not at termination. There were no other differences in hematological, clinical chemical or urinalysis parameters between treated and control animals.

Absolute and relative weights of the heart, kidney, liver, spleen and gonads were reduced in high dose animals. Those of the liver and spleen were reduced in low dose animals.

Histopathological evaluations revealed increased cellularity in the thyroid/parathyroid, cloudy swelling in the liver and nephrosis in both treated and control animals. Neither the incidence nor the severity of these lesions was greater in treated animals compared to controls.

Residue data for treated groups indicated moderate bromine residues in

Test condition	<p>Residue data for treated groups indicated moderate bromine residues in muscle, liver and fat in rats treated with 100 ppm (0.218 ppm, 0.08 ppm and 5.05 ppm, respectively) or 1000 ppm (0.66, 0.10 and 16.86 ppm, respectively) at termination of treatment. After 6 weeks of withdrawal, all residues were markedly reduced or negative in all tissues [except the fat tissue which still had a low level residue (1.5 ppm in low dose animals and 5.38 ppm in high dose animals)]. The 12 and 18 week average withdrawal values for liver and muscle were still 0. At 12 weeks, the average bromine level in fat from low and high dose animals was 1.04 and 1.98 ppm, respectively. At 18 weeks, bromine levels in fat in were slightly higher than at 12 weeks (1.45 and 3.41 ppm, respectively).</p> <p>: Male weanling rats (50 +/- 10g) were randomly divided into 15 per test group and a group of 25 controls. Test animals received either 100 or 1000 ppm test material in the basal diet. Control animals received basal diet alone. Body weights and food consumption were recorded weekly. Blood and urine were collected from five rats per group after 7 and 28 days of treatment. Blood was analyzed for red and white blood cell counts, hemoglobin, packed cell volume, urea nitrogen, total protein, diphosphoglycerate and glutamic oxaloacetic transaminase, and urine was analyzed for blood, bilirubin, ketones, glucose, albumin and pH.</p> <p>When exposure was terminated, 5 rats/treatment were euthanized. The remaining rats were continued on diet (without test material). Heart, liver, spleen, kidney and gonads from the terminated rats were weighed and these organs plus brain, pituitary, lymph nodes, salivary glands, lungs, stomach, small intestine, colon, mesenteric lymph nodes, pancreas, adrenals, urinary bladder, skeletal muscle and bone marrow were examined histologically. Muscle, liver and fat samples from these animals were analyzed for bromine.</p> <p>Two rats/treatment were euthanized after 2 and 6 weeks of withdrawal and others were euthanized at 12 and 18 weeks of withdrawal for analysis of bromine in muscle, liver and fat. An additional group of 5 animals per concentration (referred to as rerun animals) was fed test diet for 4 weeks and euthanized after 2 weeks of withdrawal to provide sufficient tissue for analysis of bromine at the 2-week withdrawal time point.</p>
Test substance	: The test material was referred to as sample 4884.
Reliability	: (3) invalid. No documentation is given proving that the test substance contained CAS No. 37853-59-1
18.09.2002	(26)
Species	: rat
Sex	: male/female
Strain	: other: Charles River CD
Route of admin.	: oral feed
Exposure period	: 28 day
Frequency of treatment	: daily
Post obs. period	: 6 weeks
Doses	: 1000 ppm
Control group	: yes, concurrent no treatment
NOAEL	: = 1000 ppm
Method	: other
Year	: 1975
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Remark	: The effect of test material on variables other than body weight and food consumption were not determined. The NOAEL listed is for effects on body weight and food consumption. Therefore, it cannot be considered to be a reliable NOAEL for other potential effects.

Based on average food consumption and body weight data, the doses in mg/kg were 75.2 for males and 89.4 for females.

Result	: mg/kg were 75.2 for males and 89.4 for females. : There were no deaths. There were no compound-related changes in general behavior or appearance, body weight, food consumption or survival. Slight increases in average bromine content were found in the fat samples from treated males (4.1 ppm vs. 1.3 ppm in controls) and females (5.3 ppm vs. 1.4 ppm in controls) following 4 weeks of exposure. There was a reduction in the bromine content of the fat samples of treated rats at each interval of analysis during the compound withdrawal period. After 18 weeks of withdrawal, the bromine content of fat from treated males (1.05 ppm) and females (1.79 ppm) was considered to be within normal limits.
Test condition	: Fifty male (192 - 233 g) and 50 female (146 - 176 g) Charles River SD rats were used in the study. Twenty five animals of each sex were given 1000 ppm test material in the diet for 28 days. The other animals (controls) were fed basal diet only. The test diet was prepared weekly by mixing the test material with fresh basal diet in a blender. After 28 days, 5 males and 5 females from each group were euthanized. The rest of the test animals were placed on basal diet. Five animals/sex/group were euthanized after 6, 12, and 18 weeks after being off of the test diet. Weights of animals were measured before treatment and weekly thereafter. Food consumption was measured weekly. Samples of liver and fat from all animals were frozen. Liver samples from animals euthanized after 28 days of treatment with the test diet and after 6 weeks of withdrawal and fat samples from all animals were analyzed for bromine. Bromine was analyzed by neutron activation.
Reliability	: (2) valid with restrictions. The purity of the test material (Firemaster 680) was not verified.
18.09.2002	(37)
Species	: rat
Sex	: male/female
Strain	: other: Charles River CD
Route of admin.	: oral feed
Exposure period	: 14 days
Frequency of treatment	: daily
Post obs. period	:
Doses	: 0.5, 1.0, 5.0 and 10% in diet
Control group	: yes, concurrent vehicle
NOAEL	: = 10 %
Method	: other
Year	: 1975
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Remark	: The cause of death in the animal that died (at 5%) could not be determined. Since the higher dose (10%) did not cause death, the NOAEL is considered to be 10% by the summary preparer.
Result	: One male rat treated with 5.0% died. There were no differences in general behavior and appearance, body weights, food consumption or gross pathology between treated and control animals.
Test condition	: Firemaster 680 was evaluated in a 14-day range finding study in Charles River CD rats. The test material was fed in diets at dosage levels of 0.5, 1.0, 5.0 and 10% to groups of 5 male (85-128 g) and 5 female (76-104 g) rats. Rats were observed daily, and body weights and food consumption were monitored weekly.
Reliability	: (2) valid with restrictions. The purity of the test material was not verified.
18.09.2002	(41)
Species	: rat
Sex	: male/female
Strain	: other: Spartan

5. Toxicity

Id 37853-59-1

Date 18.09.2002

Route of admin.	: inhalation
Exposure period	: 4 hours/day, 5 days/week for 3 weeks
Frequency of treatment	: 4 hours/day, 5 days/week
Post obs. period	: none
Doses	: 5, 20 mg/l
Control group	: yes, concurrent vehicle
NOAEL	: < 5 mg/l
LOAEL	: = 5 mg/l
Method	: other
Year	: 1975
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Remark	: The lack of statistical analyses makes it difficult to determine if changes in certain variables were significant and/or related to test material administration. The results of the urinalysis were difficult to assess because abbreviations were not defined. None of the changes in hematologies, blood chemistries or urinalyses were considered by the investigators to be related to exposure to the test material. The findings in the lung are commonly observed after exposure to particulates.
Result	<p>: There were no deaths during the study. Clinical observations noted in all groups included clear nasal discharge, soft stool and respiratory congestion. Nasal porphyrin discharge was noted at a higher frequency in treated rats compared to controls. A few treated animals exhibited ocular porphyrin discharge. One rat exposed to 5 mg/l test material had a yellow discharge from the anus for 1 one day only. There was no effect of treatment on body weight or food consumption. There was a slight, dose-dependent decrease in leukocytes in females exposed to 5 mg/l (mean $9.77 \times 10^3/\text{cmm}$) or 20 mg/l (mean $8.49 \times 10^3/\text{cmm}$) compared to controls (mean $10.49 \times 10^3/\text{cmm}$). Serum pyruvic transaminase was greater in female rats exposed to 5 (mean 21 U/ml) or 20 mg/l (mean 23 U/ml) compared to control (mean 14 U/ml), but was less than control (35 U/ml) in males exposed to 5 (25 U/ml) or 20 mg/l (30 U/ml). High dose males had an increased incidence of albumin (5 treated vs. 2 controls), slight-trace occult blood (3 treated vs. 0 controls), epithelial cells (4 occasional and 1 minimal to moderate treated vs. 2 occasional controls) and calcium oxalate crystals in the urine (4 occasional treated and 1 control).</p> <p>No gross lesions or changes were seen in rats exposed to the test material. Although the investigators stated that there was no effect of treatment on organ weights, males exhibited a dose-dependent increase in absolute lung weight compared to controls. The average lung weight in males exposed to 5 and 20 mg/l were 1.6 and 1.75 g (compared to 1.44 g in controls). Microscopic findings were limited to the lungs of treated animals. All rats from the two experimental groups (except one in the 5 mg/l group) had scattered foci of foamy alveolar macrophages in their lungs. These cells were also seen in several control animals. However, in controls, the foam cells were associated with mononuclear inflammatory cells in perivascular infiltrates and were not the predominant cell type in the inflammatory foci (with the exception of one control animal). In controls, the primary type of cells in the foci was lymphocytes. In most treated animals, the foamy alveolar macrophage was the predominant cell type and frequently was the only cell type in the cellular foci scattered throughout the lung.</p>
Test condition	: Fifteen animals sex (205 - 254 g) were acclimated for 10 days, following which the animals were divided into three groups of 5 male and 5 female rats each. Each group was placed in a sealed 59.1 liter glass chamber and was exposed by inhalation to the test material as a dust (at 5 or 20 mg/l) or to air only for 4 hours/day, 5 days/week for 21 days. In order to prevent "piling up" during the exposure, the rats were separated by sex into 4 units of 2 or 3 rats each. Addition of the test material into the chamber atmosphere was controlled by a Wright Dust Feeder. Dried and filtered air

atmosphere was controlled by a Wright Dust Feeder. Dried and filtered air was passed through the mechanism and directly into the exposure chamber. Air flow was regulated with a flowmeter.

Each rat was observed for general appearance, behavior and signs of toxicity prior to, during and immediately after each daily exposure. Individual body weights and food consumption were recorded weekly. On Day 20 of the study, 24-hour fasting blood samples were obtained from all rats and analyzed for hemoglobin, hematocrit, total erythrocyte count, and total and differential leukocyte count. Biochemical analyses performed on serum included urea nitrogen, glucose, alkaline phosphatase, glutamic oxaloacetic transaminase and pyruvic transaminase. Urine (time of collection was not stated) was analyzed for volume, specific gravity, pH, color and appearance, albumin, glucose, bilirubin and occult blood. Sediment was examined microscopically.

Animals were euthanized after 21 days of exposure. Selected organs (spleen, liver, adrenals, kidneys, heart, lung, thyroid/parathyroid and brain) were collected and weighed at necropsy. Both absolute and relative organ weights were calculated. Nasal turbinates, trachea, lung, spleen, pancreas, stomach, duodenum, colon, mesenteric lymph node, liver, adrenals, kidneys, urinary bladder, ovaries or testes, bone marrow, heart, mediastinal lymph node, thyroid/parathyroid, eye, brain and pituitary from control and high-dose animals were fixed and examined microscopically. Sections of lung from the animals exposed to 5 mg/l also were examined.

Test substance	: The test material was a commercial material (Firemaster 680). It was micronized by the supplier.
Reliability	: (2) valid with restrictions. Particle size was not listed. Purity was not verified. Data were not examined statistically.
18.09.2002	(38)
Species	: rabbit
Sex	: male/female
Strain	: New Zealand white
Route of admin.	: dermal
Exposure period	: 6 hours/day
Frequency of treatment	: 5 days/week for 4 weeks
Post obs. period	: none
Doses	: 50, 500 and 5000 mg/kg/day
Control group	: other: concurrent group received saline
NOAEL	: = 5000 mg/kg bw
LOAEL	: > 5000 mg/kg bw
Method	: other
Year	: 1975
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Remark	: The erythema was considered to be related to administration of the saline vehicle. The weight loss and diarrhea observed in one high dose male were not considered by the investigators to be related to administration of the test material.

The lack of statistical analyses makes it difficult to determine if changes in hematological, urinalysis or clinical chemistry variables were significant and/or related to test material administration.

Result	: There were no mortalities or clinical signs that were considered to be related to test material administration. Incidental findings included one mid dose female that had a clear or thick white nasal discharge throughout the study period. One high dose male rabbit had diarrhea from the 4 th to 9 th day of study, and one high dose female exhibited dehydration on the 4 th and 5 th days of the study.
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Most rabbits in the control and treated groups exhibited very slight to slight

Test condition

Most rabbits in the control and treated groups exhibited very slight to slight erythema during the study. One rabbit exposed to 5000 mg/kg/day had very slight to moderate erythema. No significant differences were noted in the degree of erythema observed before or after each daily application.

Changes in body weights were similar between groups with the exception of one high dose male that lost 713 g during the study. This rabbit lost 628 g during the first week of the study and had diarrhea from the 4th to 9th day. Body weights of this animal during the 2nd, 3rd and 4th weeks of the study were stable.

There were no changes in hematological, biochemical or urinalysis parameters, organ weights or histopathology that were attributable to test material administration.

- : Twelve male (2730-3320 g) and twelve female (2176-3014 g) New Zealand White rabbits were acclimated for 21 days before treatment. The test material was applied at 50, 500 and 5000 mg/kg/day, 5 days/week for a total of 4 weeks to dosage groups of 3 male and 3 female rabbits. Individual daily doses were based on body weights obtained weekly. A control group (3 males, 3 females) received normal saline only (at the volume applied to the high dose animals). The dorsal skin of each rabbit (approximately 10% of the body surface) was clipped. The skin of half of the animals in each group was abraded twice weekly during the study and shaved as necessary. Materials were evenly distributed with a glass rod. The animals were immobilized during the 6 hour contact period, then the backs were washed with tepid tap water.

The rabbits were observed daily for changes in behavior and appearance and signs of systemic toxicity. Dermal observations were conducted prior to and following the contact period. Blood and urine samples were collected during acclimation and after 14 and 28 days of treatment. Blood was analyzed for hemoglobin, hematocrit, total erythrocyte count, and total and differential leukocyte counts. Biochemical analyses performed on serum included urea nitrogen, glucose, alkaline phosphatase, glutamic oxaloacetic transaminase and pyruvic transaminase. Urine was analyzed for volume, specific gravity, pH, color and appearance, albumin, glucose, bilirubin and occult blood. Sediment was examined microscopically.

Animals were euthanized after 28 days on the study. Selected organs (spleen, liver, adrenals, kidneys, heart, lung, thyroid/parathyroid and brain) were collected and weighed at necropsy. Both absolute and relative organ weights were calculated. Brain, peripheral nerve, eye, lung, spleen, pancreas, stomach, duodenum, colon, lymph node, thymus, liver, heart, gallbladder, adrenals, kidneys, urinary bladder, ovaries or testes, skeletal muscle, skin, bone marrow, thyroid and pituitary from control and high-dose animals were fixed and examined microscopically. Sections of skin, liver, kidney and bone marrow from animals exposed to 50 and 500 mg/l also were examined.

**Test substance
Reliability**

- : The test material was a commercial material (Firemaster 680).
: (2) valid with restrictions. Purity was not verified. Data were not examined statistically.

18.09.2002

(42)

5.5 GENETIC TOXICITY 'IN VITRO'**Type**

- : Ames test

System of testing

- : S. typhimurium strains TA98, TA100, TA1535 and TA11537; preincubation

Concentration

- : 100, 333, 1000, 3333 and 10000 micrograms/plate

Cytotoxic conc.

- : > 10000 micrograms/plate

5. Toxicity

Id 37853-59-1

Date 18.09.2002

Metabolic activation	: with and without
Result	: negative
Method	: other
Year	: 1987
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Result	: The highest dose that did not form a precipitate was 333 micrograms/plate. None of the concentrations tested caused an increase in the number of mutants in the absence or presence of 10% rat or hamster liver S-9. All positive controls induced at least a 2-fold increase in the number of mutants with respect to the vehicle control.
Test condition	: Test material was dissolved in DMSO and incubated with <i>S. typhimurium</i> strains TA98, TA100, TA1535 and TA1537 at 100, 333, 1000, 3333 or 10000 micrograms/ml with or without S-9 from Aroclor 1254-induced rat or hamster liver (10%) for 20 min at 37 degrees C without shaking. Top agar was added and the contents of the tubes were mixed and poured onto the surfaces of petri dishes that contained Vogel-Bonner medium. The colonies present after 2 days of incubation at 37 degrees were hand-counted if there was a precipitate; otherwise automatic colony counters were used. Tests were performed in triplicate. Concurrent solvent (DMSO) and positive controls were run. The positive controls in the absence of S-9 were sodium azide (TA1535 and TA100), 9-aminoacridine (TA97 and TA1537), and 4-nitro-o-phenylenediamine (TA98). The positive control in the presence of S-9 was 2-aminoanthracene for all strains. A chemical was judged to be a mutagen if a dose-related increase over the solvent control was observed and weakly mutagenic if a low-level dose response was seen in duplicate tests. A test was considered questionable if the number of mutants at a single dose was elevated or if an increase that was not dose-related was seen.
Reliability	: (2) valid with restrictions. Test material purity was not listed.
18.09.2002	(45)
Type	: <i>Salmonella typhimurium</i> reverse mutation assay
System of testing	: Plate assay (overlay method), strains TA98, TA100, TA1535, TA1537, TA1538
Concentration	: 0.25, 0.5, 5.0, and 50 micrograms/plate
Cytotoxic conc.	: > 50 micrograms/plate
Metabolic activation	: with and without
Result	: negative
Method	: other
Year	: 1976
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Result	: The test compound did not demonstrate dose-dependent mutagenic activity in any of the strains and was considered by the authors to be non-mutagenic under the test conditions. In the test without metabolic activation, the number of mutants in control strains TA1535, TA1537, TA1538, TA98 and TA100 were 24, 13, 12, 22 and 139, respectively. The number of mutants in each of these strains treated with 0.25, 0.5, 5 or 50 micrograms/plate ranged from 15-24, 14-16, 10-12, 18-21 and 125-141, respectively. In the test with metabolic activation, the number of mutants in control strains TA1535, TA1537, TA1538, TA98 and TA100 were 12, 22, 16, 35 and 206, respectively. The number of mutants in each of these strains treated with 0.25, 0.5, 5 or 50 micrograms/plate ranged from 11-17, 11-22, 6-16, 36-38 and 170-231, respectively. In each strain, the positive controls induced at least a 7-fold increase over the number of mutants.
Test condition	: Approximately 1 x 10E9 cells from a log phase culture of each strain were added to test tubes containing 2.0 ml of molten agar supplemented with biotin and a trace of histidine. In tests without metabolic activation, four dose levels of the test material (0.25, 0.5, 5 and 50 micrograms/plate) were

dose levels of the test material (0.25, 0.5, 5 and 50 micrograms/plate) were added to the contents of the appropriate tubes and poured over the surfaces of selective agar plates. In tests with activation, S-9 and required cofactors were added to the overlay tubes. S-9 was prepared from the liver of Sprague-Dawley male rats that were injected with Aroclor 1254 (500 mg/kg) 5 days before euthanization. The four dose levels of the test material were added to the appropriate tubes, which were then mixed and the contents poured over the surface of a minimal agar (selective medium) plates and allowed to solidify. One test plate for each test material concentration, solvent control (DMSO) and positive control was run for each strain. In the experiments without S-9, the positive controls were 10 microliters/plate methylnitrosoguanidine for TA1535 and TA100, 10 microliters/plate quinacrine mustard for TA1537, and 100 micrograms/plate nitrofluorene for TA1538 and TA100. In the presence of S-9, the positive controls were anthramine for TA1535 and TA100, 8-aminoquinoline for TA1537 and 2-acetylaminofluorene for TA1538 and TA98 (all at 100 micrograms/plate). The plates were incubated for 48 to 72 hours at 37 degrees C, then scored.

Reliability : The presence of a dose-related increase in the number of mutants was indicative of a positive response.
 : (2) valid with restrictions
 Higher concentrations that did not produce toxicity should have been used in the test. More than one test per concentration should have been performed. Purity of the test material was not verified.

18.09.2002 (3)

5.6 GENETIC TOXICITY 'IN VIVO'

Type : other
Remark : There are no data for this endpoint
 18.09.2002

5.7 CARCINOGENITY

5.8 TOXICITY TO REPRODUCTION

Type : other:examination of reproductive organs from 90-day study
Species : rat
Sex : male/female
Strain : other: Charles River
Route of admin. : oral feed
Exposure period : 90 day
Frequency of treatment : daily in feed
Premating exposure period
Male :
Female :
Duration of test : 90 days
Doses : 0.1, 1.0 and 10%
Control group : yes, concurrent no treatment
NOAEL Parental : = 10 %
Method : other
Year : 1977
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Remark	<p>: The NOAEL listed is for effects on reproductive organs. Other effects of treatment are described in section 5.4. The effect of the material on mating was not characterized.</p> <p>Concentrations of test material in diets were not verified analytically. It is assumed (but not stated) that control animals were pair fed. Based on average food consumption and body weight data, the .01, 1.0 and 10% doses in mg/kg were 71.7, 729 and 8329 for males and 84.6, 874 and 9364 for females, respectively.</p> <p>The test was originally planned to be a 90-day test. Animals were maintained on test diet for an additional 16 days due to an unavoidable scheduling conflict with the necropsy.</p>
Result	<p>: There were no effects of treatment on weights or pathology of the testes, prostate, prostatic urethra or epididymis in males or the ovaries and uterus of females.</p>
Test condition	<p>: One hundred-twenty rats (60/sex; 21 days of age) were acclimated for 8 days and randomly divided into 1 control and 3 test groups (15/sex/group). The 3 test groups received 0.1, 1.0 and 10.0% test material in the diet for 106 days. Test diets were prepared by blending the appropriate amount of test material with standard rat ration in a high-speed blender. Each rat was given an amount of diet sufficient for 1 week's ad libitum feeding. Rations were checked daily to ensure that they were sufficient. Fresh diets were prepared weekly. Control animals were given basal diet without test material.</p> <p>Animals were weighed on the first day of testing and weekly thereafter. Food consumption data were collected weekly from 5 individual rats/sex/group. Rats were observed daily for death or abnormal reactions. Fasted blood and urine samples were collected from 10 rats/sex from the control and high dose groups after 40 days of treatment and from all groups after 84 days. Blood samples were analyzed for total and differential leukocyte count, erythrocyte count, hemoglobin, hematocrit, glucose, serum alkaline phosphatase, serum glutamic pyruvic transaminase, and blood urea nitrogen. Urine samples were analyzed for glucose, albumin, pH, specific gravity and microscopic elements (eg. crystals).</p> <p>After being on test for 106 days, surviving rats were euthanized and necropsied. Animals that died during the study were also necropsied if autolysis did not occur. The weights of the brain, gonads, heart, liver, kidneys, and spleen of each rat were recorded. The adrenals, aorta (thoracic), brain, cecum, colon, esophagus, eyes (with optic nerves), gonads (testes, prostate, prostatic urethra and epididymis in males and ovaries and uterus in females), heart, kidneys, liver, lung, lymph nodes (cervical, mesenteric), skeletal muscle, pancreas, peripheral nerve (sciatic), pituitary, prostate, salivary gland (submaxillary, sublingual, parotid), small intestine, spinal cord, spleen, sternum (bone marrow), stomach, thyroid, trachea and urinary bladder of control and high dose animals were examined histologically. Sections of liver from 10 rats/sex of the other test groups also were examined.</p> <p>Body weight, hematologic, clinical chemical, and organ weight data were analyzed by one way analysis of variance. Significant effects were further analyzed by either the Tukey's (for equal population size) or Scheffe's (for unequal population size) multiple comparison test. Organ to body weight and organ to brain weight ratios were analyzed by the Kruskal-Wallis Strategic Test. Significant effects were further analyzed by the Kruskal-Wallis Multiple Comparison Test. Differences from control were designated as being significant at either the $p < 0.05$ or $p < 0.01$ level. Historical control data were consulted in some instances.</p>
Test substance	<p>: The test material was a commercial product (Firemaster 680).</p>

5. Toxicity

Id 37853-59-1

Date 18.09.2002

Reliability : (2) valid with restrictions. The effect of the material on mating was not characterized. The purity of the test material was not verified.
18.09.2002 (24)

5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species : rat
Sex : female
Strain : other: Charles River CD
Route of admin. : gavage
Exposure period : gestation days 6 through 15
Frequency of treatment : daily
Duration of test : to Gestation day 20.
Doses : 100, 1000 and 10,000 mg/kg/day
Control group : yes, concurrent vehicle
NOAEL Maternalt. : = 1000 mg/kg bw
NOAEL Teratogen : = 10000 mg/kg bw
Method : other
Year : 1979
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : The significance of the increased number of high dose animals with red vaginal discharge compared to controls is not clear, since there was no increase in postimplantation losses or differences in uterine condition between high dose and control animals at cesarean section. The authors suggest that the observation may have resulted from decreased grooming.

The increase in the number of implantations at the high dose was not considered to be related to test material since it occurred prior to test material administration.

Result : Maternal: There were no deaths. There were no changes in appearance or behavior attributable to treatment with FM 680 at 100 or 1000 mg/kg/day. Slightly reduced mean maternal body weight gains during treatment (not significant) and a slight increase in the occurrence of red vaginal discharge were observed in the 10,000 mg/kg/day group as compared to the control. The number of animals exhibiting this condition was not listed in the report. The number of gravid animals ranged from 22 (at 1000 mg/kg) to 24 (for all other groups) out of 25. All gravid animals delivered live fetuses. The number of live fetuses/dam ranged from 11.9 for the controls to 13.3 for dams treated with 10,000 mg/kg/day test material. There were no statistically significant differences between groups in the mean number of viable or nonviable fetuses, early or late resorptions, or corpora lutea. There were no statistically significant differences in the mean number of implantations in the 100 or 1000 mg/kg/day groups compared to the control group. There was a statistically significant increase in the mean number of total implantations/dam in the high dose group compared to controls (14.1 vs. 12.4).

Fetal: There were no significant differences in the male to female sex ratio or mean fetal body weights between treated groups and the control. The total number of fetuses (litters) with malformations in the control, low-, mid- and high- dose groups was 3(3), 1(1), 1(1) and 0(0). There were no statistically significant differences in the number of litters or the number of fetuses with anomalies between treated and control animals. There was a slight increase (not significant) in the number of animals (litters) with unossified Sternebra Number 5 and/or 6 in fetuses from rats treated with the low dose of material [18(11)] compared to control [12(6)]. The incidence of this variation in rats treated with 1000 [11(8)] or 10000 mg/kg/day [13(7)] was similar to control. The incidences of other variations were similar between control and treated animals.

Test condition

were similar between control and treated animals.

: One hundred female Charles River CD rats (approximately 8-9 weeks old) were acclimated for a minimum of 18 days prior to mating. One female was mated with a male of the same strain. The day of mating was determined by daily inspection for a copulatory plug or by a vaginal smear for sperm. The day a plug or sperm was found was designated day 0 of gestation. Mated rats were then housed individually.

The bred rats were randomly assigned to 4 groups (25/treatment). Test material was administered by gavage (at a constant volume of 10 ml/kg/day) at 100, 1000 and 10,000 mg/kg/day from day 6 through 15 of gestation. The test material was finely ground with a mortar and pestle and suspended daily in corn oil. A control group received the vehicle at 10 ml/kg/day. Individual doses were based on body weights taken on gestation days 6, 9, and 12. During gestation, females were observed daily for mortality and clinical signs of toxicity. Body weights were recorded on days 0, 6, 9, 12, 16 and 20 of gestation. Animals were euthanized on day 20 of gestation and Cesarean sections were performed.

The number of viable and nonviable fetuses, early and late resorptions, corpora lutea and total implantations were recorded. The fetuses were weighed, sexed and examined for external abnormalities. Approximately one-third were placed in Bouin's fixative and examined later for visceral abnormalities and variations. The remaining two-thirds were fixed in alcohol, macerated with potassium hydroxide, stained with Alizarin Red S and examined for skeletal anomalies and variations.

Data for male to female sex ratios, number of litters and number of fetuses with anomalies of treated and control groups were compared using the Chi-square test with Yates correction for 2 x 2 contingency tables and/or Fisher's exact probability test. The proportions of early resorbed fetuses and postimplantation losses of these groups were compared using the Mann-Whitney U-test. The mean numbers of corpora lutea, total implantations and viable fetuses were compared by analysis of variance (one-way), Bartlett's test for homogeneity of variances, the appropriate t-test (for equal and unequal variances), and Dunnett's multiple comparison table to determine the significance of differences between means. Fetal body weights were compared by analysis of variance (hierarchical classification), t-test and Dunnett's multiple comparison tables. The level of significance was $p < 0.05$.

Test substance**Reliability**

18.09.2002

: The test material was listed as FM 680, lot #61114 -F.
 : (2) valid with restrictions. Purity of the test material was not verified.

(18)

Species

: rat

Sex

: female

Strain

: other: Charles River CD

Route of admin.

: gavage

Exposure period

: gestation days 6 through 15

Frequency of treatment

: daily

Duration of test

: Gestation Day 20

Doses

: 30, 100, 300, 1000, 3000 and 10000 mg/kg/day

Control group

: yes, concurrent vehicle

NOAEL Maternalt.

: = 10000 mg/kg bw

NOAEL Teratogen

: = 10000 mg/kg bw

Method

: other

Year

: 1978

GLP

: no data

Test substance

: as prescribed by 1.1 - 1.4

Remark

: The decrease in fertility seen in animals treated with 100 mg/kg/day was not related to the test material since it was given after mating. The authors attributed the early delivery from one rat treated with 1,000 mg/kg/day to be

Result

- attributed the early delivery from one rat treated with 1,000 mg/kg/day to be due to an inaccurate determination of copulation. However, the fact that this was the only animal that had a nonviable fetus suggests that the animal may have aborted. This does not appear to be related to test material, since two higher doses did not induce early delivery or fetal death.
- : Survival in all groups was 100%. The test material had no effect on body weight gains, appearance or behavior. The mean number of fetuses from rats treated with 0, 30, 100, 300, 1,000, 3,000 or 10,000 mg/kg/day were 12.8, 12.4, 13.0, 14.8, 14.0, 13.6, and 14.4, respectively. All fetuses were viable (except one from a rat treated with 1,000 mg/kg/day that delivered early; see above). There was no effect of test material on the number of resorptions (average ranged from 0 at 100 mg/kg/day to 0.8 at 1,000 mg/kg/day; all were late), implantations (average ranged from 12.8 at 30 mg/kg/day to 15.2 at 300 mg/kg/day) or corpora lutea (average ranged from 13.0 at 30 mg/kg/day to 15.5 at 1,000 mg/kg/day).

Test condition

- One animal in the 1,000 mg/kg/day group delivered 14 viable and one nonviable fetus after 7 days of treatment. Three animals in the 100 mg/kg/day group were nongravid.
- : Thirty-five female Charles River CD rats (approximately 10 weeks old) were acclimated for a minimum of 2 weeks prior to mating. One female was mated with a male of the same strain. The day of mating was determined by daily inspection for a copulatory plug or by a vaginal smear for sperm. The day a plug or sperm was found was designated day 0 of gestation. Mated rats were then housed individually. An additional 5 females were bred later and treated with 10,000 mg/kg/day test material (see below).

The bred rats were randomly assigned to 6 groups (5/treatment). Due to lack of toxicity at the tested doses, one additional test group of 5 rats was later assigned. Test material was administered by gavage (at a constant volume of 25 ml/kg/day) to the original study animals at 30, 100, 300, 1,000, and 3,000 and to the additional group of animals at 10,000 mg/kg/day from days 6 through 15 of gestation. The test material was finely ground with a mortar and pestle and suspended daily in corn oil. A control group (from the original lot) received the vehicle at 25 ml/kg/day. Individual doses were based on body weights taken on gestation days 6, 12, and 15. During gestation, females were observed daily for mortality and clinical signs of toxicity. Body weights were recorded on days 0, 6, 12, 15 and 20 of gestation. Animals were euthanized on day 20 of gestation and the abdominal and thoracic cavities were examined. The numbers of viable and nonviable fetuses, early and late resorptions, total implantations and corpora lutea were recorded.

Test substance
Reliability
18.09.2002

- : The test material was listed as FM 680, lot #61114-F.
- : (2) valid with restrictions. Purity of the test material was not verified.

(17)

5.10 OTHER RELEVANT INFORMATION**Type**

- : other:pharmacokinetics in rats

Remark

- : This study was conducted to help determine if performance of a chronic study was warranted. The fact that the material was poorly absorbed suggested to the authors that such a test was not necessary.

Test condition

- : Feed preparation: [14C]FF-680 was administered to rats in feed for 1 day at target concentrations of 0.05, 0.5 or 5%, and for 10 days at a concentration of 0.05%. For the animals used for CO₂ collection, the concentration of FF-680 in the feed sticks was 0.169%. Radiolabeled material was mixed with unlabeled material before being mixed with feed.

For the 1-day feeding study, the specific activity values for the diluted

isotopic material were 1.8, 0.2, and 0.04 microcuries/micromole for the 0.05, 0.5 and 5% concentrations. For the 10-day feeding study, the specific activity was 1.14 microcuries/micromole for the 0.05% concentration. For the biliary excretion study, the specific activity was 0.17 microcuries/micromole.

The amounts of the diluted isotopic material and feed needed to make each concentration were preweighed. An equivalent amount of preweighed feed was added to the finely ground isotopic material and mixed with a spatula. Portions of feed were continuously added and mixed until the appropriate amount of feed had been added. For the animals used for CO₂ collection, feed containing 0.5% test material was mixed with gelatin to prepare feed sticks suitable for use in metabolism cages. For the biliary excretion study, diluted isotopic material was suspended in corn oil at a concentration of 49.93 mg/ml for a dose level of 200 mg/kg. Dosing volume was approximately 4 ml/kg.

Dose formulations were analyzed to determine the concentration and radiochemical purity of test material in the diet. At least 5 separate samples were analyzed. Combusted samples and those extracted with tetrahydrofuran were analyzed by radiochemical methods and HPLC, respectively.

Study conduct: Four rats per group were assigned to receive 0.05, 0.5 and 5% test material in the diet for 24 hours (test 1), and five rats received 0.05% test material in the diet for 10 days (test 2). Urine and feces were collected from test 1 animals 0-18, 18-24, 24-48, 48-72 and 72-96 hours after they were given the test diet. Test 1 animals were euthanized 96 hours after being placed on the test diet. Urine and feces were collected daily and at termination (Day 10) from test 2 animals. Cages from test 1 and 2 animals were washed with water at time of termination. At termination, test 1 and 2 rats were anesthetized and blood was collected by cardiac puncture. Liver, kidney, heart, lung, brain, adipose tissue (sample), skeletal muscle (sample), spleen and thymus were removed, weighed and stored at -10 degrees C until analysis.

Four animals that had been fitted with bile cannulas were given 200 mg/kg test material in corn oil by gavage (test 3). Bile was collected 0-15, 15-30, 30-60, 60-90, 90-120, 120-180, 180-240, 240-300 and 300-360 min after treatment. These animals were euthanized after the last bile collection.

An additional group of 3 rats was given 0.169% test material for 24 hours for analysis of expired ¹⁴CO₂ (test 4). Expired CO₂ was collected in 8M KOH 0-18, 18-24, and 24-48 hours after animals were placed on the test diet.

Analyses: Radioactivity in duplicate samples of urine, bile, 8 M KOH traps, cage rinses, and either combusted or solubilized feces and tissue samples was measured using liquid scintillation counting. The recovery efficiency of the combustion system was determined daily.

Urine (0-18 hour collection period) was combined from each of the 4 animals given 0.05% or 5.0% material (test 1) and the 5 animals in test 2 (day 8 collection). The urine was lyophilized to dryness and the residue was extracted twice with methanol. The extracts were concentrated and filtered. Total recovery of radioactivity was 93, 95 and 94% for the 0.05% and 5.0% test 1 animals and the test 2 animals, respectively. Feces from these animals were similarly combined, lyophilized to dryness and extracted with tetrahydrofuran. Total recovery of radioactivity in fecal samples was 96, 99 and 105% for the 0.05% and 5.0% test 1 animals and the test 2 animals, respectively. The extracts were concentrated under vacuum and analyzed by HPLC.

Calculations: The quantity of radioactivity consumed by each rat was calculated from the weight of the radiolabeled feed consumed in 24 hr, the weighed concentration of test material in the feed, and the specific activity of the material. Concentrations of radioactivity in tissue samples processed by solubilization were corrected for background values obtained from tissues from untreated animals. Samples having counts less than twice background were assigned values of 0 for the calculations.

Test substance : [Ring-¹⁴C]FF-680, 70 mCi/mmol, was 97.6% pure, and unlabeled FF-680 was 100% pure (verified by HPLC and gas chromatography). FF-680 is a commercial product consisting of 100% 1,2-bis(2,4,6-tribromophenoxy)ethane (according to the MSDS).

Conclusion : The results showed that test material was poorly absorbed from the GI tract following administration in the diet for one day. After 10 days of administration, very low levels of material were found in tissues.

Reliability : (1) valid without restriction

09.09.2002 (25)

Type : other: pharmacokinetics in rats

Test condition : Test material: The analytical reference standard (27.5 mg) was weighed in a 10 ml volumetric flask that was filled with chloroform and shaken. One half ml of the stock solution was pipetted into several vials and 125 micrograms of ¹⁴C labeled test material in chloroform was added to each vial. Each vial then contained 1.5 mg of test material having a specific gravity of 1.91 mCi/mM. About 0.25 ml of vegetable oil was incorporated into each vial and the chloroform was evaporated. Each vial contained the dose for a single rat.

Test conduct: Eight female and 2 male Holtzman's albino rats (200-300 g) were acclimated in metabolism cages at least 2 days before use. The rats were divided into 4 groups of two females each (Groups I-IV) and one group of the two males (Group V). Food and water were withdrawn for at least 8 hours prior to dosing. Rats were lightly anesthetized with ethyl ether and given a single dose of test material by oral intubation. Groups I, II, III and IV were given doses of 5.42, 4.30, 3.60 and 3.96 mg/kg and Group V was given 4.57 mg/kg test material. One female was given a sham dose. Food and water were provided ad libitum until termination. Urine and feces were collected daily. Blood was collected from the tails at 1, 2, 4, 8, 17, 24, 48, 72, and 96 hours after dosing from animals in Groups II and III and 144 hours in animals in Group IV. Animals were weighed and anesthetized at termination and blood was collected by cardiac puncture. Animals in Groups I - V were terminated 48, 96, 144, 240 and 240 hours after dosing, respectively. Blood, heart, lungs, muscle, fat, gonads, uterus, spleen, kidney, liver and brain were excised and frozen until analysis.

Radioassay: A portion (0.2 to 0.5 ml) of each urine sample was counted directly in scintillation cocktail. From 300 to 600 mg of feces, rat tissues or blood were combusted with a biological material oxidizer. The efficiency of the oxidation process was greater than 90%. The resulting ¹⁴CO₂ was trapped and scintillation cocktail was added automatically. Duplicate samples of urine, feces, blood and tissues were analyzed. Samples were usually counted for 10 minutes. Quench correction was applied to all samples. Counting efficiency (70-85%) was determined by an on-line computation program.

Data were analyzed by a computer program designed to compute several pharmacokinetic parameters.

Test substance : The test materials were ¹⁴C[1,2, bis (2,4,6-tribromophenoxy)ethane](CAS No. 37853-59-1) with a specific activity of 23 mCi/mM (purity not stated) and an analytical reference standard of 1,2, bis (2,4,6-tribromophenoxy)ethane synthesized by the manufacturer.

Reliability : (2) valid with restrictions. The purity of the test material was not verified.

5. Toxicity

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(9)

Type : other: residue accumulation/depletion in rats
Test condition : A tissue residue accumulation/depletion study was conducted on groups of rats (120 males, 120 females) fed either 0 or 1000 ppm Firemaster 680 for 24 weeks followed by a 58 week recovery period. Groups (5 rats/sex/treatment) were euthanized at 4, 8, 12, 16, 20 and 24 weeks of testing and at 2, 4, 9 1/2, 12, 18 or 58 weeks of recovery.
Reliability : (2) valid with restrictions. The purity of the test material (Firemaster 680) was not verified.

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(21)

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 - (14) EPIWIN KOWWIN (v1.66).
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7.1 END POINT SUMMARY

7.2 HAZARD SUMMARY

7.3 RISK ASSESSMENT